

THOMAS L. GARTHWAITE, M.D. Director and Chief Medical Officer

FRED LEAF
Chief Operating Officer

COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES 313 N. Figueroa, Los Angeles, CA 90012 (213) 240-8101

April 29, 2004

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, CA 90012

Dear Supervisors:

ACCEPT ONE NOTICE OF GRANT AWARD FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE; ONE GRANT AWARD FROM FEDERAL CENTERS FOR DISEASE CONTROL AND PREVENTION; AUTHORIZATION TO INCREASE THE STAFFING ORDINANCE BY 4 CLASSIFICATIONS; AND APPROVAL OF 8 HIV/AIDS SERVICE AMENDMENTS

(All Districts) (4 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

- 1. Delegate authority to the Director of Health Services, or his designee, to accept the attached Notice of Grant Award (NGA) No.1 H97HA1290-01-00 from the U.S. Health Resources and Services Administration (HRSA) Special Projects of National Significance (SPNS), further described in Attachment A-1, in the amount of \$300,000 for the budget period of September 30, 2003 through August 31, 2004, following review and approval by County Counsel and notification to the Board offices.
- 2. Delegate authority to the Director of Health Services, or his designee, to accept substantially similar SPNS awards for the continuing project period, September 1, 2004 through August 31, 2007, in an amount not to exceed \$900,000, following review and approval by County Counsel and notification to the Board offices.
- 3. Approve a Fiscal Year (FY) 2003-04 appropriation adjustment in the amount of \$142,000 to authorize increased expenditure authority for Services and Supplies for the SPNS Prevention for Positives project grant.
- 4. Delegate authority to the Director of Health Services, or his designee, to accept the attached NGA No. 200-2003-02366 from the Federal Centers for Disease Control and Prevention (CDC) Advancing HIV Prevention Initiative (AHP), further described in Attachment A-2, in the amount of \$1,214,404, for the budget period of September 15, 2003 through September 14, 2004, following review and approval by County Counsel and notification to the Board offices.

Gloria Molina First District

Yvonne Brathwaite Burke Second District

> Zev Yaroslavsky Third District

Don Knabe Fourth District

Michael D. Antonovich Fifth District

- 5. Delegate authority to the Director of Health Services, or his designee, to accept substantially similar AHP awards for the continuing project period, September 15, 2004 through September 14, 2005, in an amount not to exceed \$1,214,404, following review and approval by County Counsel and notification to the Board offices.
- 6. Approve a FY 2003-04 appropriation adjustment in the amount of \$598,000 to authorize increased expenditure authority for Services and Supplies for the CDC and Prevention Routine HIV Rapid Testing in Clinical Settings program.
- 7. Delegate authority to the Director of Health Services, or his designee, to execute five amendments for HIV/AIDS AHP services, effective the date of Board approval through September 14, 2005, for a total maximum obligation of \$1,119,018, and three amendments for HIV/AIDS SPNS services, effective date of Board approval through August 31, 2007, for a total maximum obligation of \$868,475, following review and approval by County Counsel.
- 8. Authorize the Department of Health Services to fill four positions: one (1) Public Health Nurse, one (1) Senior Typist Clerk and two (2) Administrative Assistant II payroll classifications, in excess of what is provided in the Department's staffing ordinance pursuant to Section 6.06.020 of the County Code, pending allocation by the Department of Human Resources.

PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTIONS:

Acceptance of the NGA awards from the CDC and HRSA will ensure the continuation of the HIV/AIDS demonstration projects which are expected to research, evaluate, and demonstrate the outcome and cost effectiveness of interventions supported by these funds and provide detailed information that could be used to implement these strategies in jurisdictions throughout the country. These types of demonstration projects also assist the Department of Health Services (DHS) with the determination of the best service practices which are subsequently incorporated into standard service delivery procedures.

Special Projects of National Significance (SPNS)

Acceptance of the SPNS award funds will ensure the implementation and evaluation of a new prevention practice at selected study sites. The HRSA SPNS funds are awarded for integrating prevention activities into the primary health care environment and measuring the effectiveness of those activities. The evaluation will assess sustainability of risk reduction behavior through a series of one baseline and three follow up surveys. More than 450 clients will be interviewed at baseline, and qualitative interviews will be conducted with both providers and clients. Los Angeles County is one of 15 four-year SPNS efforts funded in the nation for this type of demonstration project.

Advancing HIV Prevention Initiative (AHP)

Acceptance of the CDC AHP award will fund the adaptation and implementation of strategies for the newly announced Centers for Disease Control and Prevention AHP Initiative which carries the objective of reducing the number of new HIV infections occurring each year. This project will provide detailed information that will be used to make HIV testing a routine part of medical care and aid in the prevention of new infections by working with people diagnosed with HIV and their partners. One of the key priorities of the CDC is the provision of prevention education to people who are HIV positive and the recruitment of their participation in the effort to stem the rates of infection.

Acceptance of the CDC and HRSA awards will also authorize the Department to fill four (4) grant-funded positions. These positions are essential to project completion. The four additional positions will assist with the implementation, program planning and development for the AHP and SPNS programs.

Board approval of the recommended actions will allow DHS to continue the provision of vital HIV/AIDS services.

FISCAL IMPACT/FINANCING:

The SPNS program cost is \$300,000 per year for a total program cost of \$1,200,000, which is 100% offset with HRSA award funds. The annual cost for the AHP program is \$1,214,404 for a total program cost of \$2,428,808, which is 100% offset with CDC funds. Funding for the programs were not included in the FY 03-04 Budget, but will be requested in future fiscal years as awarded. The recommended actions will not increase net County cost.

The five amendments for HIV/AIDS AHP services, effective the date of Board approval through September 14, 2005, have a total maximum obligation of \$1,119,018 and the three amendments for HIV/AIDS SPNS services, effective date of Board approval through August 31, 2007, for a total maximum obligation of \$868,475.

Appropriation adjustments for Services and Supplies are attached in the amounts of \$142,000 and \$598,000 for FY 2003-04, for the SPNS and AHP programs, respectively. The revised allocations were not anticipated at the time the Department's budget was adopted.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

Since 1983, the County has accepted financial support from the CDC to enhance HIV/AIDS prevention activities. This support has included both the award of grants and assignment of federal personnel or other resources.

The Department received the SPNS NGA on September 25, 2003 and Los Angeles County's Office of AIDS Programs and Policy (OAPP) was one of fifteen four-year projects funded through the HRSA program. This project entails recommended funding for four years to develop and implement technological innovations to improve service delivery, integrate prevention messages into the primary health setting, conduct extensive evaluation of the effectiveness of the innovations, and the dissemination of those findings. The evaluation will assess sustainability of risk reduction behavior through a series of one baseline and three follow-up surveys. More than 450 clients will be interviewed at baseline, and qualitative interviews will be conducted with both providers and clients.

The initial budget period for this program is September 30, 2003 through August 31, 2004, with the complete project term of September 30, 2003 through August 31, 2007. Attachment A-1 provides additional information.

The CDC AHP project entails implementation and evaluation of interventions using consequence-framed messaging during clients' medical appointments at AltaMed Health Services and Los Angeles County Harbor-UCLA Medical Center. Northeast Valley Health Services will serve as the control-comparison site, and the evaluation data will measure the extent of client behavioral changes and the effectiveness of the interventions.

Acceptance of the award and approval of the eight amendments will authorize the Department to amend the existing contracts with AltaMed Health Services and Northeast Valley Health Services to allow participation in the project, and authorize Childrens Hospital Los Angeles to conduct evaluation, data collection, training and consultation services for this project.

The delegation of authority to the Director of Health Services to accept amendments to the SPNS and AHP awards will reduce the need to return to the Board for subsequent grant awards and allow the acceptance of appropriation adjustments that do not require Board approval.

The four new additional positions will assist with the implementation, program planning and development for the CDC AHP and SPNS programs, respectively.

Attachments A through A-2, B, C, C-1, D and Exhibits I through X provide additional information.

DHS will advise the Board of the acceptance of any amendments that augment the award within 30 days of receipt.

County Counsel has reviewed and approved the NGAs (Exhibits I through II) and amendments (Exhibits III through X) as to form.

CONTRACTING PROCESS:

Los Angeles County had approximately 30 days to submit a proposal to the CDC in response to the release of their Advancing HIV Prevention Requests for Proposals (RFP). Existing contractors were identified who were best positioned to partner with the OAPP Office and who could facilitate the submission of a competitive grant proposal. It was not possible for the Department to release and complete an RFP solicitation within that timeframe due to the fact that the competitive solicitation process generally requires 12 months to complete.

The three contractors chosen for the SPNS program are existing contractors who are best positioned to facilitate the initiation of the provision of the SPNS services. As it was the goal of the Department to initiate services and begin the assessment and integration of prevention activities immediately, it was not possible to release and complete an RFP solicitation process prior to the initiation of services. The three clinics participating in the SPNS program were selected based on the following criteria: 1) having a client population of more than 400 patients annually, 2) project design called for one community clinic and one County hospital site, 3) Agency demonstrated consistent high-quality service delivery, 4) Agency represented both geographic and client diversity."

IMPACT ON CURRENT SERVICES (OR PROJECT):

The grant funds awarded to the County will facilitate the review, use and evaluation of innovative practices enhancing prevention for positives efforts at primary health care settings. Scientific evaluation of these activities will reveal whether or not these types of patient education can yield sustainable behavior changes, and whether or not medical clinics will support and advocate ongoing prevention patient education.

The SPNS and AHP project funds will ensure the continuation of preventions services vital to the ongoing effort to prevent HIV infection among County residents at risk for HIV/AIDS.

When approved, this Department requires three signed copies of the Board's action.

Respectfully subpartted,

Thornas L. Garthwaite, M.D. Director and Chief Medical Officer

TLG:ks

Attachments

c: Chief Administrative OfficerCounty CounselExecutive Officer, Board of Supervisors

AHP_SPNSNGA2004.KS.wpd

SUMMARY OF AMENDMENTS

1. <u>TYPE OF SERVICE</u>:

HIV/AIDS Demonstration Projects

2. AGENCY NAME AND CONTACT PERSON:

A. AIDS Healthcare Foundation

6255 West Sunset Boulevard, Suite 2100

Los Angeles, California 90028-8073

Attention:

Michael Weinstein,

President and Chief Executive Officer

Telephone:

(323) 462-2273

B. AltaMed Health Services Corporation

500 Citadel Drive, Suite 490

Los Angeles, California 90040

Attention:

Castulo de la Rocha, President/CEO

Telephone:

(323) 889-7310

C. Childrens Hospital Los Angeles

4650 Sunset Boulevard, Mailstop #2

Los Angeles, California 90054-0700

Attention:

Walter W. Noce, Jr., President/CEO

Telephone:

(213) 660-2450

D. Clinica Monsenor Oscar A. Romero

123 South Alvarado Street

Los Angeles, CA 90057

Attention:

J. F. Gotsill, Co-Executive Director

Attention:

Grace Floutsis, M.D., Co-Executive Director

Telephone:

(213) 201-2730

E. The Los Angeles Free Clinic

8405 Beverly Boulevard

Los Angeles, CA 90048-3476

Attention:

Abbe Land, Co-Executive Director

Attention:

Jeff Bujer, Co-Executive Director

Telephone:

(323) 653-8622

F. The Los Angeles Gay and Lesbian Community Services Center,

d.b.a. The Los Angeles Gay and Lesbian Center

1625 Schrader Boulevard

Los Angeles, CA 90028

Attention:

Lorri L. Jean, Executive Director

Telephone:

(323) 993-7609

G. Los Angeles SHANTI Foundation

1616 North La Brea Avenue, Suite 200

Los Angeles, California 90028

Attention:

Marc Haupert, Executive Director

Telephone:

(323) 962-8197

SUMMARY OF AMENDMENTS

H. Northeast Valley Health Corporation

1172 North Maclay Avenue

San Fernando, California 91340

Attention:

Kimberly Wyard, CEO

Telephone:

(818) 898-1388

3. TERMS:

Project Period: September 30, 2003 through August 31, 2007 (HRSA SPNS)

Budget Period - Term 1: September 30, 2003 through August 31, 2004 (HRSA SPNS) Term 2: 09/01/04 - 08/31/05 Term 3: 09/01/05 - 08/31/06 Term 4: 09/01/06 - 08/31/07

Project Period: September 15, 2003 through September 14, 2005 (CDC AHP) Budget Period: September 15, 2003 through September 14, 2004 - Term 1 Budget Period: September 15, 2004 through September 14, 2005 - Term 2

4. FINANCIAL INFORMATION:

	Term 1	Term 2	Term 3	Term 4	<u>Totals</u>
Maximum County Obligation:	\$1,514,404	\$1,514,404	\$300,000	\$300,000	\$3,628,808
CDC	(\$1,214,404)	(\$1,214,404)	(\$ 0)	(\$ 0)	(\$2,428,808)
HRSA	(\$ 300,000)	(\$ 300,000)	(\$300,000)	(\$300,000)	(\$1,200,000)
Net County Cost:	\$ -0-	\$ -0-	\$ -0-	\$ -0-	\$ -0-

Amount of Financial Assistance:

\$1,214,404 Annually - CDC

\$ 300,000 Annually - HRSA

5. GEOGRAPHIC AREA SERVED:

SPA's 2, 7, and 8

Supervisorial Districts 1, 3, and 4

6. <u>ACCOUNTABLE FOR MONITORING AND EVALUATION:</u>

Charles L. Henry, Director

Office of AIDS Programs and Policy

7. APPROVALS:

Office of AIDS Programs and Policy:

Charles L. Henry, Director

Public Health:

John F. Schunhoff, Ph.D., Chief of Operations

Contracts and Grants Division

Irene E. Riley, Director, Contracts Administration

County Counsel (approval as to form):

Kelly Auerbach-Hassel, Deputy County Counsel

SUMMARY OF GRANT AWARD

1. TYPE OF SERVICE/PROJECT:

Special Projects of National Significance

2. AGENCY ADDRESS AND CONTACT PERSON:

Health Resources and Services Administration Division of Grants Management Operations 5600 Fishers Lane, Room 11A-16 Rockville, Maryland 20857

Rockville, Maryland 2085

Attention:

Pamela Baker, Grants Management Specialist

Telephone:

(301) 443-0197

3. TERMS:

Project Period:

September 30, 2003 through August 31, 2007

Budget Period:

September 30, 2003 through August 31, 2004 (Term 1)

Term 2:

09/01/04 - 08/31/05 Term 3: 09/01/05 - 08/31/06 Term 4: 09/01/06 - 08/31/07

4. FINANCIAL INFORMATION:

Totals Term 1 Term 2 Term 3 Term 4 Maximum County Obligation: \$300,000 \$300,000 \$300,000 \$300,000 \$1,200,000 HRSA: (\$300,000)(\$300,000) (\$300,000)(\$300,000) (\$1,200,000) Net County Cost: \$ -0-\$ -0-\$ -0-\$ -0--0-

Amount of Financial Assistance:

\$300,000 Annually - HRSA

5. GEOGRAPHIC AREA SERVED:

SPA's 2, 7, and 8 Supervisorial Districts 1, 3, and 4

6. ACCOUNTABLE FOR MONITORING AND EVALUATION:

Charles L. Henry, Director, Office of AIDS Programs and Policy

7. APPROVALS:

Office of AIDS Programs and Policy:

Charles L. Henry, Director

Public Health:

John F. Schunhoff, Ph.D., Chief of Operations

Contracts and Grants Division

Irene E. Riley, Director

County Counsel (approval as to form):

Kelly Auerbach-Hassel, Deputy County Counsel

SUMMARY OF NOTICE OF GRANT AWARD

CDC, ADVANCING HIV PREVENTION INITIATIVE GRANT NO. 200-2003-02366

AGENCY ADDRESS AND CONTACT PERSON:

Centers for Disease Control and Prevention Acquisition & Assistance Branch A 2920 Brandywine Road Atlanta, Georgia 30341-5539 Attention: Allyson Brown, Contracting Officer

Telephone: (770) 488-2649

1. TITLE OF PROJECT:

Advancing HIV Prevention Initiative

2. TERM:

Project Period:

September 15, 2003 through September 14, 2005

Budget Period:

September 15, 2003 through September 14, 2004 - Term 1

September 15, 2004 through September 14, 2005 - Term 2

3. FINANCIAL INFORMATION:

	Term 1	Term 2	<u>Totals</u>
Maximum County Obligation: CDC	\$1,214,404 <\$1,214,404>	\$1,214,404 <\$1,214,404>	\$2,428,808 <\$2,428,808>
Net County Cost:	\$ -0-	\$ -0-	\$ -0-

Amount of Financial Assistance:

\$1,214,404 Annually - CDC

4. GEOGRAPHIC AREA TO BE SERVED:

Countywide

5. ACCOUNTABLE FOR MONITORING AND EVALUATION:

Charles L. Henry, Director, Office of AIDS Programs and Policy

6. APPROVALS:

Office of AIDS Programs and Policy:

Charles L. Henry, Director

Public Health Programs and Services:

John F. Schunhoff, Ph.D., Chief of Operations

Contracts and Grants Division:

Irene E. Riley, Director, Contracts Administration

County Counsel (review):

Kelly M. Auerbach-Hassel, Deputy County Counsel

	AD AD	VANCING]	ADVANCING HIV PREVENTION		HIV/AIDS S	PECIAL PR	OJECTS OF	AND HIV/AIDS SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE SERVICES	GNIFICANCE	SERVICES	SERVICES .
Agency	Exhibit		Alloc	Allocation			Funding	Supervisorial	Service	Target	Performance as of
		Term 1	Term 2	Term 3	Term 4	Totals	Source	District	Planning Area	Population	September 30, 2003
AIDS Healthcare Foundation H-207279-3	H	\$ 99,487	\$165,813			\$265,300	CDC	1s, 2nd, 3rd, and 5th Districts	SPAs 1, 4, 5, & 6	Partner Counseling and Referral Services clients	Agency is meeting goals.
AltaMed Health Services Corporation H-209203-12	II	\$ 32,083	\$ 35,000	\$35,000	\$ 20,417	\$122,500	HRSA	1st District	SPA 7	All Clinic Patients	Agency is meeting goals.
Childrens Hospital Los Angeles * H-212033-2	Ш	\$254,06	\$185,181	\$165,055	\$ 89,179	\$ 693,475	HRSA	1 st , 3 rd , and 4 th Districts	SPAs 2, 7,	All Participating Clinics and their Patients	Agency is meeting goals.
Clinica Monsenor Oscar A. Romero H-213466-2	N.	\$ 85,457	\$142,427			\$227,884	CDC	3 rd District	SPA 4	Random Sample of Clinic Patients	Agency needs to improve performance regarding service goals. Improvement plan implemented.
Los Angeles Free Clinic H-207530-2	>	\$ 85,457	\$142,427			\$227,884	CDC	3 rd District	SPA 4	Random Sample of Clinic Patients	Agency is meeting most goals. Improvement plan implemented.

ADVANCING HIV PREVENTION AND HIV/AIDS SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE SERVICES

Agency	Exhibit			Allocation			Funding	Supervisorial	Service	Target Population	Performance as of
		Term 1	Term 2	Term 3	Term 4	Totals	Source	District	Planning Area		September 30, 2003
Los Angeles Gay and Lesbian Center H-211828-3	VI	\$ 99,487	\$165,813			\$265,300	CDC	3 rd District	SPA 4	Partner Counseling and Referral Services clients	Agency is meeting goals.
Los Angeles SHANTI Foundation H-207280-3	VII	\$ 49,744	\$ 82,906			\$132,650	CDC	3 rd District	SPA 4	Partner Counseling and Referral Services clients	Agency is meeting goals.
Northeast Valley Health Corporation H-209014-9	VIII	\$ 13,750	\$ 15,000	\$ 15,000	\$ 8,750	\$ 52,500	HRSA	3 rd District	SPA 2	All Clinic Patients	Agency is meeting goals.

\$1,987,493, 100% offset with federal CDC AHP and HRSA SPNS funds. Total maximum County obligation:

(1,119,018)

(868,475) -0-\$ Less HRSA funds: County AIDS funds: Less CDC funds:

*Sub-contractors include University of Southern California School of Medicine and Los Angeles County - Harbor/University of California,

Los Angeles Medical Center through Research and Education Institute.

Los Angeles County Chief Administrative Office Grant Management Statement for Grants Exceeding \$100,000

Department: Health	Services				
Grant Project Title and 1	Description				
Special Projects of Natio	onal Significance (SPNS)				
Funding Agency	Program (Fed. Grant #/State Bill or C	Code #)	Grant .	Acceptance	e Deadline
HRSA	1 H97HA01290-01-00		None		
Total Amount of Grant 1	Funding: \$1,200,000	County Match Requ	iiremen	nts N/A	<u> </u>
Grant Period: 09/30/0	Begin Date: 09/30/03	End Date		08/31/07	
Number of Personnel Hi	ired Under this Grant:	Full Time	3	Part Time	e
	Obligations Imposed on the County	When the Grant Ex	<u>pires</u>		
Will all personnel hired	for this program be informed this is a	grant funded program?	Yes	X No	
Will all personnel hired	for this program be placed on tempora	ry ("N") items?	Yes	X No	
Is the County obligated	to continue this program after the gran	t expires	Yes	No	X
If the County is not oblig	gated to continue this program after the	e grant expires, the De	partme	nt will:	
a). Absorb the program	cost without reducing other services		Yes	No	X
b). Identify other revenu	ie sources		Yes	X No	Armon estate a servicio de la companio de la compa
(Describe) Identify	and apply for other grant funding				
c). Eliminate or reduce,	as appropriate, positions/program cost	ts funded by this grant.	. Yes	X No	
Impact of additional pers	sonnel on existing space: *Current	space will accommod	ate all i	ndicated s	staff.
Other requirements not r	mentioned above: None	1			
Department Head Signat	ture // //	//	Date	e <u>5/4,</u>	104

Special Projects of National Significance and Advancing HIV Prevention Initiative Fiscal Year 2003-2004

Positions In Excess Of What is Currently Authorized In The Department Of Health Services Staffing Ordinance

(Section 6.06.020 Of The County Code)

Special Projects of National Significance (SPNS)

<u>Public Health Nurse – 1 Position</u>

This position will assist in the program planning, development and implementation of grants funded by SPNS from Health Resources and Services Administration (HRSA). The duties for this position will include managing the effective integration of prevention strategies and interventions in HIV primary care settings by providing oversight of these demonstration projects, and developing project implementation strategies and plans.

Senior Typist Clerk – 1 Position

The primary responsibilities for this position will include performing highly skilled typing duties, managing telephone traffic and carrying out clerical duties for a team of Program Managers as well as a Program Assistant under the direction of a Unit Supervisor.

ADVANCING HIV PREVENTION INITIATIVE (AHP)

Administrative Assistant – 2 Positions

Both positions will act in the capacity of a Project Assistant and will support the work of the Coordinator and Clinical and Quality Assurance Coordinator positions responsible for implementing routine rapid HIV testing services and/or partner counseling and referral services (PCRS) and for facilitating the completion of all associated project evaluation and reporting requirements associated with the AHP initiative and as described by the CDC. Both positions will also be responsible for meeting and managing all data collection, entry, and reporting requirements associated with this project including client risk assessments, evaluation forms, non-names reporting forms, and partner elicitation, contact, follow-up and notification forms.

Los Angeles County Chief Administrative Office Grant Management Statement for Grants Exceeding \$100,000

Department: Health	Services						
,							
Grant Project Title and							
Advancing HIV Prevent	tion Initiative (AHP)	(
Funding Agency	Program (Fed. Grant #/State Bill or	Code #)	Grant	Acceptance	e Deadline		
CDC	200-2003-02366		None				
<u> </u>							
Total Amount of Grant	Funding: \$2,428,808	County Match Requ	iiremei	nts N/A			
Grant Period:	Begin Date: 09/15/03	End Date	: :	09/14/05			
Number of Personnel H	ired Under this Grant:	Full Time	3	Part Time			
	Obligations Imposed on the Count	ty When the Grant Ex	<u>pires</u>				
Will all personnel hired	for this program be informed this is a	a grant funded program?	Yes	X No			
Will all personnel hired	for this program be placed on tempor	rary ("N") items?	Yes	X No			
Is the County obligated	to continue this program after the gra	nt expires	Yes	No	X		
If the County is not obligated to continue this program after the grant expires, the Department will:							
a). Absorb the program	cost without reducing other services		Yes	No	X		
b). Identify other revenu	ie sources		Yes	X No			
(Describe) Identify	and apply for other grant funding						
c). Eliminate or reduce,	as appropriate, positions/program co	sts funded by this grant.	Yes	X No			
-							
Impact of additional per	sonnel on existing space: *Currer	nt space will accommod	ate all	indicated st	aff.		
Other requirements not i	mentioned above: None						
Department Head Signat	ture A Chew	1	Dat	te5/9	Joef		

COUNTY OF LOS ANGELES

REQUEST FOR APPROPRIATION ADJUSTMENT

DEPT'S.

DEPARTMENT OF

Health Services

April 14,

Kg 2004

AUDITOR-CONTROLLER.

THE FOLLOWING APPROPRIATION ADJUSTMENT IS DEEMED NECESSARY BY THIS DEPARTMENT. WILL YOU PLEASE REPORT AS TO ACCOUNTING AND AVAILABLE BALANCES AND FORWARD TO THE CHIEF ADMINISTRATIVE OFFICER FOR HIS RECOMMENDATION OR ACTION.

ADJUSTMENT REQUESTED AND REASONS THEREFOR

4-VOTE

SOURCES:

Office of AIDS Programs and Policy

Revenue - Federal Other

A01-HS-25770-9001

\$598,000

USES:

Office of AIDS Programs and Policy

Services and Supplies

A01-HS-25770-2000

\$598,000

TOTAL:

\$598,000

TOTAL:

\$598,000

Justification:

This adjustment is required to increase Office of AIDS Programs and Policy's (OAPP) Services and Supplies for Centers for Disease Control and Prevention Routine HIV Rapid Testing in Clinical Settings and Integration of Routine Rapid HIV Testing into PCRS for Fiscal Year 2003-04. The funds are granted through the Centers for Disease Control and Prevention. The funds are granted directly to OAPP for the additional expenses and Programs to be incurred. This action was not anticipated at the time the budget was adopted.

EM:br 04/14/04

Efrain Munoz, Chief

DHS-Controller's Division

CHIEF ADMINISTRATIVE OFFICER'S REPORT

REFERRED TO THE CHIEF ADMINISTRATIVE OFFICER FOR	ACTION	APPROVED AS REQUESTED	(AS REVISED
	RECOMMENDATION	April 15 2004	DARTO DANIE DE LA TIVE DE LA CONTROL DE LA C
AUDITOR-CONTROLLER	BY Hele Jeng	APPROVED (AS REVISED): BOARD OF SUPERVISORS	19
NO. 269	APKIL 13 12004	ВҮ	DEPUTY COUNTY CLERK

COUNTY OF LOS ANGELES

REQUEST FOR APPROPRIATION ADJUSTMENT

Health Services DEPARTMENT OF

April 14, 33 2004

AUDITOR-CONTROLLER.

THE FOLLOWING APPROPRIATION ADJUSTMENT IS DEEMED NECESSARY BY THIS DEPARTMENT. WILL YOU PLEASE REPORT AS TO ACCOUNTING AND AVAILABLE BALANCES AND FORWARD TO THE CHIEF ADMINISTRATIVE OFFICER FOR HIS RECOMMENDATION OR

ADJUSTMENT REQUESTED AND REASONS THEREFOR

4-VOTE

SOURCES:

Office of AIDS Programs and Policy

Revenue - Federal Other

A01-HS-25770-9001

\$142,000

TOTAL:

\$142,000

USES:

Office of AIDS programs and Policy

Services and Supplies

A01-HS-25770-2000

\$142,000

TOTAL:

<u>\$142,000</u>

Justification:

This adjustment is required to increase Office of AIDS Programs and Policy's Services and Supplies for the Special Projects of National Significance (SPNS), Prevention for Positives grant for Fiscal Year 2003-04. The funds are granted through the Human Resources and Services Administration. The funds are granted directly to OAPP for the additional expenses and programs to be incurred. The action was not anticipated at the time the budget was adopted.

EM:br 04/14/04

Efrain Munoz, Chief

Dés Controller's Division

CHIEF ADMINISTRATIVE OFFICER'S REPORT

REFERRED TO THE CHIEF ADMINISTRATIVE OFFICER FOR— ACTION RECOMMENDATION AUDITOR-CONTROLLER BY

APPROVED AS REQUESTED

APPROVED (AS REVISED) BOARD OF SUPERVISORS

BY

DEPUTY COUNTY CLERK

2. PROGRAM CFDA: 93.928 1, DATE ISSUED: MM/DD/YYYY 08/16/2003 3. SUPERCEDES AWARD NOTICE dated: expect that any editions or restrictions previously imposed remain in a

5. FORMER GRANT NUMBER:

DEPARTMENT OF HEALTH AND HUMAN SERVICES HEALTH RESOURCES AND SERVICES ADMINISTRATION



NOTICE OF GRANT AWARD AUTHORIZATION (Legislation/Regulation) Public Health Service Act, Title XXVI, Section 2618a

6. PROJECT PERIOD: (MM/DD/YYYY) FROM: 09/30/2003 THROUGH: 08/31/2007

7. BUDGET PERIOD: (MWDDYYYY)

4. GRANT NUMBER: 1 H97HA01290-01-00

FROM: 09/30/2003 THROUGH: 08/31/2004

8. TITLE OF PROJECT (OR PROGRAM): Special Projects of National Significance 10. DIRECTOR: (PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR) 9. GRANTEE NAME AND ADDRESS: DEPT OF HEALTH SERVICES, COUNTY OF LOS ANGELES ROBERT FISH DEPT OF HEALTH SERVICES, COUNTY OF LOS ANGELES 600 SO COMMONWEALTH AVENUE FL 6TH 600 S COMMONWEALTH AVENUE FL 6TH LOS ANGELES, CA 90022-5152 UDS# LOS ANGELES, CA 90005-4001 12. AWARD COMPUTATION FOR FINANCIAL ASSISTANCE 11. APPROVED BUDGET: (Excludes Direct Assistance) a. Authorized Financial Assistance This Period [X] Grant Funds Only [] Total project costs including grant funds and all other financial b. Less Unobligated Balance from Prior Budget Periods participation i. Additional Authority ii. Offsel a. Salaries and Wages; 20.00 c. Unawarded Balance of Current Year's Funds 2 D DD b. Fringe Benefits: d. Less Curnulative Prior Award(s) This Budget 2 0.00 c. Total Personnel Costs: d. Consultant Costs; \$ 0.00 8. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION \$ 0.00 e. Equipment f. Supplies: 2 0.00 13. RECOMMENDED FUTURE SUPPORT: (Subject to the availability of funds and satisfactory progress of project) 5 0.00 g. Travel: h. Construction/Alteration and Renovation: 3 0.00

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a. Amount of Direct Assistance

o. TOTAL DIRECT COSTS: 00.000,000 2 p. INDIRECT COSTS: (Rate: % of S&W/TADC) \$ 0.00 q. TOTAL APPROVED BUDGET: \$ 300,000.00 i. Less Non-Federal Resources: 00.00

Funds c. Less Cumulative Prior Awards(s) This Budget

b. Less Unawarded Balance of Current Year's

d. AMOUNT OF DIRECT ASSISTANCE THIS 2 0.00 ACTION

14. APPROVED DIRECT ASSISTANCE BUDGET: (In lieu of cash)

15. PROGRAM INCOME SUBJECT TO 45 CFR PART 74, SUBPART F OR 45 CFR 92.25 SHALL BE USED IN ACCORD WITH ONE OF THE FOLLOWING ALTERNATIVES: [A]

A=Additional Cost B=Deduction C=Finance Non-Federal D=Cost Sharing or Malching E=Other

Estimated Program Income: \$ 0.00

j. Consortium/Contractual Costs:

k. Trainee Related Expenses:

m. Trainee Tullion and Fees:

il. Federal Share:

I. Trainee Stipends:

n. Traines Travel:

i. Other:

16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY HRSA, IS ON THE ABOVE TITLED PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING: D'ani propram instalishon card above o The grant program regulation clad above. C The award notice including larme and co More are confloting or otherwise inconsistent paritime applicable in the grant, the above order of decedence anall provail. Acce Yeny, noted below under REMARKS, d. 45 CFR Perl 74 or 45 CFR Penl 92 ac

REMARKS: (Other Terms and Conditions Attached [X] Yes [] No)

The budget period has administratively changed to reflect a start date of September 30 to August 31. Future budget period will be 12 months at the anticipated recommended budget level.

Electronically signed by Janica Gordon, Grants Management Officer on: 09/16/2003

17. OBJ. CLASS: 41.45 19. FUTURE RECOMMENDED FUNDING: 18. CRS-EIN: 1956000927A1

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BOARD OF SUPERVISORS OFFICIAL COPY

COUNTY OF LOS ANGELES REQUEST FOR APPROPRIATION ADJUSTMENT DEPARTMENT OF HEALTH SERVICES

Dept. No. 296

January 12, 2004

Auditor-Controller,

The following appropriation adjustment is deemed necessary by this department. Will you please report as to accounting and available balances and forward to the CHIEF ADMINISTRATIVE OFFICER for his recommendation or action.

ADJUS	STMENT RI		O AND REASONS THEREF OTE	FOR	
SOURCES: Office of AIDS Programs and Policy Revenue - Federal Other A01-HS-25770-9001	\$ 142,000	,	USES: Office of AIDS Programs Services and Supplies A01-HS-25770-2000	and Policy	142,000
Total	\$ 142,000		Total	\$	142,000
This adjustment is required to increase the Special Projects of National Signif The funds are granted through the Hur directly to OAPP for the additional expat the time the budget was adopted. CHIEF ADMINISTRATIVE OFFIC	nan Resource penses and pr	S), Preventi es and Servi rograms to t	on for Positives grant for Fisc	al Year 2003-04.	
	ction		Approved as Requested	As Revised	
Recommendation	1				
AUDITOR-CONTROLLER BY		20	CHIEF AD	MINISTRATIVE O	FFICER
CONTROLLER BY				20	
		APPR	OVED (AS REVISED) BY	19	

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17. CONTR	ACTOR'S NEGOTIATED AGREEMEN	T /Contractor in	required	18. X					
to sign this document			required			Contractor is not		this document.)	
Contractor agrees to f	urnish and deliver all items or nectorm	all the conject of	el forth or	Your offer or	5 Solicitation	Number <u>2003</u>	-N-00894		
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governed by the follow	d obligations of the parties to this contra ving documents; (a) this award/contract	ct shall be subje-	ct to and	continuation	sheets. This	s award consumr	nates the contract	of which consider	0/160
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attached or incomorati	ed by reference herein. (Attachments a	re listed herein.)						Jai y.	
TO TRAINE AND THE	LE OF SIGNER (Type or print)			20A. NAME	OF CONTRA	ACTING OFFICE	R		
John Sch	unhoff, Chief of Oper	rations		William J	I. Rvan	_			
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STANDARD FORM 26 (REV. 4-85)
Prescribed by GSA

ATTACHMENT I

BOARD OF SUPERVISORS OFFICIAL COPY

76R 352M 11/83

COUNTY OF LOS ANGELES REQUEST FOR APPROPRIATION ADJUSTMENT DEPARTMENT OF HEALTH SERVICES

Dept. No. 296

January 23, 2004

Auditor-Controller,

AUDITOR-CONTROLLER BY

The following appropriation adjustment is deemed necessary by this department. Will you please report as to accounting and available balances and forward to the CHIEF ADMINISTRATIVE OFFICER for his recommendation or action.

ADJUSTMENT REQUESTED AND REASONS THEREFOR 4 VOTE

SOURCES:			:	USES:	•		
Office of AIDS Programs:	and Policy				AIDS Programs an	d Policy	
Revenue - Federal Other					ind Supplies		
A01-HS-25770-9001	\$	598,000		A01-HS-2	25770-2000	\$	598,000
· · · · · · · · · · · · · · · · · · ·			* * .				
Total	\$	598,000			Total	-\$	598,000
					•		
Justification:						. •	*
This adjustment is required			-	•	•	• •	
Centers for Disease Contro	ol and Prevention	on Routine F	HV Rapid	Testing in C	Clinical Settings and	d Integration of	•
Routine Rapid HIV Testing	g into PCRS fo	or Fiscal Yea	r 20 <u>0</u> 3-04	. The funds	are granted throug	h the Centers for	
Disease Control and Preven	ntion. The fun	ds are grante	ed directly	to OAPP fo	r the additional exp	enses and program	ıs
to be incurred. The action v		_					
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APPROVED (AS REVISED) BY

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) COUNSELING AND TESTING SERVICES AGREEMENT

Amendment No. 2

	THIS AMENDMENT	is made and entered into this day
of _		, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	THE LOS ANGELES FREE CLINIC (hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) COUNSELING AND TESTING SERVICES AGREEMENT", dated March 26, 2002, and further identified as Agreement No. H-207530, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and the provide changes set forth herein; and

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor will participate in the Los Angeles County Eligible Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of State and/or federal Centers for Disease Control and Prevention (CDC) funds, where there is a Service Provider Network (SPN) in the SPA in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must implement a "consumer advisory committee" with

regular meetings and consumer membership as a mechanism for

continuously assessing client need and adequacy of

Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must actively collaborate and recruit referrals

from service organizations and agencies beyond the Ryan White

CARE Act service delivery system, including, but not limited

to, substance abuse, mental health, primary health care and

social services organizations.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor's referrals to and from organizations must be noted

and tracked in the OAPP service utilization data system, and

followed up in client need and adequacy of Contractor's

services, and to obtain client feedback.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties hereto agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on March 26, 2002 and continue in full force and effect through December 31, 2004. Said Agreement shall thereafter be renewed for a nine (9) month and two (2) week term effective January 1, 2005 through September 14, 2005 subject to the availability of federal, State or County funds. If such funding is not forthcoming, this agreement shall terminate on December 31, 2004. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. In any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, A-1, D, D-1, D-2 E, E-1 and E-2, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>,
 Subparagraphs E and F, shall be added to Agreement as follows:
 - "E. During the period date of Board approval through December 31, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Eighty-Five Thousand, Four Hundred Fifty-Seven Dollars (\$85,457). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 7, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Rapid HIV-1 AntiBody Test Services.
 - F. During the period January 1, 2005 through
 September 14, 2005, the maximum obligation of County for
 all services provided hereunder shall not exceed One
 Hundred Forty-Two Thousand, Four Hundred Twenty-Seven

Dollars (\$142,427). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 8, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Rapid HIV-1 AntiBody Test Services."

- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder on a feefor-service basis as set forth in Schedules 1, 2, 3, 4,

 5, and 6, and for reimbursable net cost as set forth in

 Schedules 7, and 8 and the FEE-FOR-SERVICE REIMBURSEMENT

 Paragraph of this Agreement."
- 6. Paragraph 17, <u>COST REIMBURSEMENT</u>, shall be added to Agreement as follows:
 - "17. <u>COST REIMBURSEMENT</u>: County shall compensate

 Contractor for actual reimbursable net costs incurred by

 Contractor in performing services hereunder.
 - A. Monthly Billing: Contractor shall bill County monthly in arrears. All billings shall include a financial invoice and all required

programmatic reports and/or data. All billing shall clearly reflect all required information as specified on forms provided by County regarding the services for which claims are to be made and any and all payments made to Contractor by, or on behalf of, clients/patients. Billings shall be submitted to County within thirty (30) calendar days after the close of each calendar month. Within a reasonable period of time following receipt of a complete and correct monthly billing, County shall make payment in accordance with the schedule(s) attached hereto.

B. County Audit Settlements:

- and/or County representatives finds that actual reimbursable net costs for any services furnished hereunder are lower than the payments made thereof by County, and/or if it is determined by such audit that any payments made by County for a particular service is for costs which are not reimbursable pursuant to provisions of this Agreement, then the difference shall be repaid by Contractor.
- (2) If within forty-five (45) calendar days of termination of the contract period, such audit finds

that the allowable costs of services furnished hereunder are higher than the payments made by County, then the difference may be paid to Contractor.

- C. In no event shall County be required to reimburse Contractor for those costs of services provided hereunder which are covered by revenue from or on behalf of clients/patients or which are covered by funding from other governmental contracts or grants.
- D. In no event shall County be required to pay

 Contractor more for all services provided hereunder than
 the maximum obligation of County as set forth in the

 MAXIMUM OBLIGATION OF COUNTY Paragraph of this Agreement,
 unless otherwise revised or amended under the terms of
 this Agreement.
- E. Travel costs shall be reimbursed according to applicable federal, state, and/or local guidelines.

 Prior authorization, in writing, shall be required to claim reimbursement for travel outside Los Angeles County unless such expense is explicitly approved in the contract budget. Request for authorization shall be made in writing to Director and shall include the travel

dates, locations, purpose/agenda, participants, and costs.

F. Withholding Payment:

- requirements of this Agreement and the exhibit(s) attached hereto, County may withhold any claim for payment by Contractor if any report or data is not delivered by Contractor to County within the time limits of submission as set forth in this Agreement, or if such report or data is incomplete in accordance with requirements set forth in this Agreement. This withholding may be invoked for the current month and any succeeding month or months for reports or data not delivered in a complete and correct form.
- (2) Subject to the provisions of the TERM and ADMINISTRATION Paragraphs of this Agreement, and the exhibits attached hereto, County may withhold any claim for payment by Contractor if Contractor has been given at least thirty (30) calendar days' notice of deficiencies in compliance with the terms of this Agreement and has failed to correct such

deficiencies. This withholding may be invoked for any month or months for deficiencies not corrected.

- (3) Upon acceptance by County of all report(s) and data previously not accepted under this provision and/or upon correction of the deficiencies noted above, County shall reimburse all withheld payments on the next regular monthly claim for payment by Contractor.
- (4) Subject to the provisions of the exhibits of this Agreement, if the services are not completed by Contractor within the specified time, County may withhold all payments to Contractor under this Agreement between County and Contractor until proof of such services is delivered to County.
- (5) In addition to Subparagraphs (1) through

 (4) immediately above, Director may withhold claims

 for payment by Contractor which are delinquent

 amounts due to County as determined by a cost report

 settlement, audit report settlement, or financial

 evaluation report, resulting from this or prior

 years Agreement(s).
- G. Contractor agrees to reimburse County for any federal, State, or County audit exceptions resulting from

noncompliance herein on the part of Contractor or any subcontractor.

- 7. Exhibits, E, E-1, and E-2, SCOPES OF WORK FOR HIV/AIDS COUNSELING AND TESTING RAPID HIV-1 ANTIBODY TEST SERVICES, are attached hereto and incorporated herein by reference.
- 8. Schedules 7 and 8, BUDGETS FOR HIV/AIDS COUNSELING AND TESTING RAPID HIV-1 ANTIBODY TEST SERVICES, are attached hereto and incorporated herein by reference.
- 9. Except for the changes set forth hereinabove,
 Agreement shall not be changed in any respect by this
 Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

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Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COU	JNTY OF LOS ANGELES
Ву	
_	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
THE	LOS ANGELES FREE CLINIC
	Contractor
Ву	
-	Signature
	Printed Name
Tit	cle
	(AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

DEPARTMENT OF HEALTH SERVICES

APPROVED AS TO CONTRACT ADMINISTRATION:

Irene E. Riley, Director
Contract Administration

EXHIBIT E

THE LOS ANGELES FREE CLINIC

ROUTINE HIV TESTING IN CLINICAL SETTINGS USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES AGREEMENT

- DEFINITION: Routine HIV testing in clinical 1. settings using the OraQuick Rapid HIV-1 antibody test services provide routine HIV testing to all individuals who visit a variety of clinical settings and meet eligibility criteria, pre- and post-test counseling, linked referrals to appropriate health and social services as needed by client, and the provision of appropriate HIV risk reduction intervention based on client's need. Such services shall be provided through urgent care facilities. For the purposes of this Agreement, a linked referral is any referral that is facilitated by the providers and confirmed as met by the referring agency. At a minimum, a linked referral must include: referral information provided in writing and verification regarding client's access to services. Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services are provided free of charge and on a confidential basis.
- 2. <u>PERSONS TO BE SERVED</u>: Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services shall be provided to individuals that meet the following criteria: (1) are at

least 12 years of age, (2) are not in critical condition, (3) are not previously known to be HIV infected, (4) are without unstable psychiatric condition, (5) are not under the influence of alcohol or other illicit drugs, and (6) are not identified as a prisoner or detainee in Service Planning Areas 1 through 8 of Los Angeles County.

- 3. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period date of Board approval through September 14, 2005, that portion of County's maximum obligation which is allocated under this Exhibit for routine HIV testing in clinical settings using the OraQuick rapid HIV-1 antibody test services shall not exceed Two Hundred Twenty-Seven Thousand, Eight Hundred Eighty-Four Dollars (\$227,884).
- 4. <u>COMPENSATION</u>: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedules 7 and 8.

Payment for services provided hereunder shall be subject to the provisions set forth in the <u>FEE-FOR-SERVICE</u>

<u>REIMBURSEMENT</u> Paragraph of this Agreement.

5. <u>SERVICE DELIVERY SITE(S)</u>: Contractor's facility where services are to be provided hereunder is located at: 5205 Melrose Avenue, Los Angeles, California 90038 and other sites as approved by OAPP's Director.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before terminating services at such location(s) and/or before commencing such services at any other location(s). OAPP reserves the right to approve and deny all requests and will make such decisions based on the appropriateness of the request.

6. <u>SERVICES TO BE PROVIDED</u>: During each term of this Agreement, Contractor shall provide routine HIV testing in clinical settings using the OraQuick Rapid HIV-1 antibody test to persons meeting the eligibility criteria, in accordance with procedures formulated and adopted by Contractor's staff, the Centers for Disease Control and Prevention (CDC); consistent with California law; California Department of Health Services (CDHS) - Office of AIDS (OA) guidelines and the terms of this Agreement. The Director of OAPP shall notify Contractor of any revisions to OAPP policies and procedures, which shall become part of this Agreement. Pretest and disclosure counseling shall follow Los Angeles County quidelines for HIV Prevention Counseling as adopted by the Centers for Disease Control and Prevention (CDC) and CDHS-OA. All counseling sessions shall take place in a private, faceto-face session in a closed room or area that ensures patient confidentiality. Additionally, Contractor shall provide such

services as described in Exhibits E-1 and E-2, Scopes of Work, attached hereto and incorporated herein by reference.

Minimum services to be provided shall include, but not be limited to, the following:

- A. Provide Confidential testing upon acceptance by client. Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. For those clients who whish to only be tested anonymously, a referral to an anonymous counseling and testing site shall be provided.
- B. Provide a client-centered counseling session that engages the client in a dialogue that encourages the disclosure of unique individual needs and concerns related to HIV risk and emphasizes personal options that limit or prevent transmission of HIV. Additionally, the client-centered counseling session should accomplish the following: a) improve the client's self-perception of risk; b) support behavior change previously accomplished or attempted by the client; c) negotiate a workable short-term and long-term risk reduction plan based on the client's perceived ability to change his or her behavior; d) support informed decision-making about whether to be

tested; e) obtain informed consent; f) obtain consent to draw a confirmatory test specimen in the event that the rapid test result is preliminary positive; g) review the nexus between HIV and STD infections; h) ensure that the client understands the meaning of test results, including a reactive OraQuick result requiring confirmatory testing; and i) assess the client's potential reaction to receiving a reactive rapid test. The Contractor shall fully collect client demographic information using the handheld computer system using iPAQ Pocket PCs provided by OAPP. All information reported on the approved device(s) and lab slips shall be voluntarily supplied by the client. In the event that the PDA device is not working appropriately, or the individual feels uncomfortable with the use of the PDA, a paper based data collection instrument will be made available to continue the pre-test counseling session. In the even that client level data is collected on the paper-based data collection tool, the information will be entered into a PDA prior to submission of all client level data to OAPP. Once received at OAPP, the client level data will be submitted to CDC based on their schedule of data submission.

- 7. Provide an FDA-approved Rapid HIV-1 antibody test to determine the presence of HIV antibodies. The provision of screening procedures shall be preceded by a review with the client of the following areas: a) information regarding risks and benefits of the Rapid HIV-1 antibody test; b) an explanation of the meaning of the respective test results; c) an explanation of the respective testing procedures; d) information on the importance of a confirmatory test if the test result is preliminary positive; e) a review of the HIV-antibody window period; and f) completion of OAPP-approved consent form signed by the client and maintained in the client's file in accordance with the California Code of Regulations.
 - A. The HIV Certified Counselor shall ensure to follow the steps to testing using the OraQuick rapid HIV-1 antibody test as delineated in the OraQuick package insert and in the Step-by-Step Instructions for OraQuick Rapid HIV-1 Antibody Test.
 - B. Conduct a client-centered disclosure counseling session that serves to provide the client with their results and that integrates the test result in a meaningful and productive manner based on their reported risk factors and consistent with their risk reduction

efforts. Test results shall not be mailed, nor disclosed over the phone, nor given to anyone except the client, nor given in the presence of other persons with the exceptions stipulated by California Health and Safety Codes 121010, 121015, 121020, 120975, 120980, and 120985.

The HIV Certified Counselor reviewing the client's Counseling Information shall precede the disclosure session. The HIV Certified Counselor personalizing and framing the session to the client to establish a comfortable setting by describing disclosure session steps shall precede the disclosure event. HIV Certified Counselor shall disclose the results, review the medical interpretation of the test result and assess the client's emotional state, counseling needs, understanding of the test results, need to be re-tested based on the window period and recent risk behaviors, need to test for a confirmatory test for preliminary positive results. The HIV Certified Counselor shall assess the client's understanding of and commitment to risk reduction guidelines as well as the strength of social support and plans for and consequences of disclosure to others.

- D. For clients testing HIV-positive, the following additional topics shall be covered in the disclosure session; a) need for a confirmatory test, b) information regarding the risk of HIV transmission to the fetus or newborn during pregnancy, during labor and delivery, and during the postpartum period if the individual is a woman or the male partner of a women of childbearing age; c) information on the risks of re-infection; d) written documentation of information and/or assistance with partner notification and/or linkage to Los Angeles County Department of Health Services Partner Counseling Referral Services (PCRS) and field follow-up services for assisted partner notification; e) a written assessment of the client's reaction to the positive test result to determine whether referral for psychosocial support services, including suicide prevention, is indicated.
- E. The HIV Certified Counselor shall assess the need for referrals and provide specific, written referrals with adequate linkages as appropriate. At a minimum, referrals to the following services shall be considered based on client risk and test results: risk reduction, prevention for HIV-infected persons, mental health services, partner counseling and referral

services, and tuberculosis screening and drug treatment services. For HIV-positive clients written referrals to a minimum of three (3) primary medical care providers shall be provided and any other linked referrals appropriate to the immediate health and social needs of the client. The Contractor shall document all linked referrals and referral follow-up for each person served under this Agreement. The linked referral follow-up shall include, but not be limited to, the agency the person was referred to, any appointment(s) made, no show for said appointment, and follow-up plan, if the individual failed to show for confidential testing.

- F. Contractor shall comply with the Interim
 Revision of Requirements for Content of AIDS-related
 Written Materials, Pictorials, Audiovisuals,
 Questionnaires, Survey Instruments, and Educational
 Sessions in Centers for Disease Control Assistance
 Programs, as referenced in Exhibit B.
- G. Contractor shall obtain written approval from OAPP's Director for all educational materials utilized in association with this Agreement prior to its implementation.

- H. Contractor shall submit for approval such educational materials to OAPP at least thirty (30) days prior to the projected date of implementation. For the purposes of this Agreement, educational materials may include, but not limited to, written materials (e.g., curricula, pamphlets, brochures, fliers), audiovisual materials (e.g., films, videotapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings).
- I. Failure of Contractor to abide by this requirement may result in the suspension of this Agreement at the Director's sole discretion.
- J. Contractor shall utilize funds received from County for the sole purpose of providing HIV/AIDS counseling, testing, immune assessment, and referral services.
- K. Contractor shall not utilize funds received from County for the purpose of any and all activities associated with needle exchange, including, but not limited to, purchasing and exchanging of needles.
- L. Contractor shall ensure that all staff supported by County funds are not engaged in any and all needle exchange activities.

- M. Contractor shall be responsible for reimbursing County for all funds expended on any and all activities associated with needle exchange.
- ${\tt N.}$ Any breach of these provisions shall result in the immediate termination of agreement.

8. <u>ADDITIONAL REQUIREMENTS:</u>

Offering HIV Counseling and Testing: HIV counselors shall routinely offer HIV rapid testing through two mechanisms: (1) a sampling pattern of every $3^{\rm rd}$ person to be selected from the clinic registration/sign-in sheet. This log shall contain at a minimum, the client's name and reason for visit; (2) clinician-initiated referrals for routine screening shall be made. A waiting list shall be established at each site to appropriately queue clients who have been offered and are interested in receiving an HIV rapid In the event that the HIV counselor is unavailable, clinician-initiated referrals shall be added to the waiting list. First priority will be given to those clients signed up on the waiting list. Educational posters, pamphlets and brochures describing HIV counseling and testing (specifically through the use of a rapid test), and general HIV risk information will be made available.

B. HIV counselors shall approach prospective testers and in the discretion of a private counseling room, offer a routine HIV rapid test. The counselors shall identify themselves as facility staff and inform the potential tester that routine HIV rapid testing is being made available to any individual seeking services. The counselors shall briefly explain the following:

(1) The HIV testing process:

- (a) The use of an OraQuick® rapid HIV test.

 Only confidential testing shall be offered.

 Referrals shall be provided to other clinics offering anonymous HIV testing. Counselors shall discuss the following: (1) the difference between a standard blood test, an OraSure-oral (OMT) test, and the rapid test; (2) the type and method of specimen collection; (3) the waiting time for results; (4) what different results mean; and (5) confirmatory testing.
- (b) Upon brief discussion of these topics, the counselor shall confirm the individual's willingness to discuss HIV rapid testing. Upon

consent (both verbal and written), the counselor will engage the client through the standard pretest counseling and informed consent process.

Individuals Refusing HIV Counseling and Testing: Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of nonrespondents can be evaluated. Some individuals may not wish to discuss HIV counseling and testing because they are already HIV positive. In these cases, counselors shall determine if the individual is receiving medical care for his/her HIV infection, as well as provide referrals for services, including additional medical care services, and other community and psychosocial services. If a need for such services is identified, the individual will be referred to the appropriate service provider. Referrals for medical care, social services, and mental health will be made available to all clients regardless of their decision to test. HIV counselors shall use the iPAO Pocket Personal Computers (PDA) to collect refusal information and they will also document refusal to test in the

medical record. This will ensure that negative clients who refused HIV testing are offered testing again during their next clinic visit. Linkages to non-HIV medical care and delivery of referrals shall continue regardless of the client's desire to test or not. For individuals who do not wish to consider HIV counseling and testing for reasons other than a prior HIV diagnosis, the reason for their refusal should be elicited to evaluate potential bias.

Testing: Individuals who meet the established eligibility criteria and consent to test, shall be tested for HIV using the OraQuick® rapid HIV test.

For the purposes of this agreement only confidential tests may be performed so that follow-up for provision of medical and psychosocial services may be accomplished. Clients who wish to test via an anonymous test shall be directed to other testing facilities where an anonymous test may be obtained.

All HIV counselors providing services through this project are certified HIV test counselors, trained and certified phlebotomists, and trained in Rapid HIV counseling and testing. All pre- and post-test

testing; and (3) relevant information regarding the window period. Counselors must be clearly explain that the OraQuick® rapid test only refers to obtaining results rapidly-not to reducing the time between exposure and identification of infection. If a client has had a recent exposure (less than 3 months) and their test is non-reactive, the client shall be counseled to re-test at 3 months from exposure. If the client decides to be tested with OraQuick®, counselors will: (1) ensure that the client understands the meaning of test results, including that a reactive OraQuick® result requires confirmatory testing; (2) assess client's potential reaction to receiving a reactive rapid test; (3) informed consent must be provided for confidential HIV testing according to local standards. The consent form shall also request a commitment for collection of a second specimen (serum or oral fluid) for individuals testing preliminary positive via OraQuick®. In addition, all counselors shall be required to follow local guidelines and

recommendations pertaining to HIV counseling and testing, HIV rapid testing, and Phlebotomy (both venipuncture and finger stick).

- (b) If the HIV counselor is not certified in phlebotomy or providing finger sticks, they shall escort the client to the appropriate medical or laboratory staff for a finger stick.

 Once the blood specimen is collected, the counselor shall ensure the test is processing accurately, and will return the client to the counseling room for continuation of the pre-test counseling session.
- (c) Once the tests are fully run

 (approximately 20-40 minutes after initial blood sample is collected and placed in the testing mechanism), the counselor shall return to the laboratory (or designated testing room) to obtain the test results. The counselor shall return to the private counseling room to disclose the test results to the patient.

C. <u>Materials Required for Testing:</u>

(1) The following materials are provided to the site: (1) The OraQuick® Rapid HIV-1 Antibody Test

packaged in a divided pouch that contains the device (with absorbent packet) in one side and the developing solution in the other; (2) reusable test stands; (3) specimen collection loops; (4) subject information pamphlets; (5) package insert; and (6) external controls (set of positive and negative).

The following materials are not provided to the site but are required. Agencies must have all of these materials prior to conducting testing; (1) latex, vinyl or nitrile disposable gloves; (2) sterile retractable lancets; (3) timer or watch capable of timing 20-60 minutes; (4) clean, disposable, absorbent workspace cover ("chux" pads); (5) antiseptic wipes; (6) sterile gauze pads (2"x2"); (7) small adhesive bandages; (8) bio-hazard sharps container and trash bags; (9) surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide); (10) alcohol-based waterless hand cleanser; (11) laboratory grade thermometers to measure storage temperature of test devices and controls and temperature of testing location; (12) required forms; and (13) a flashlight to illuminate

the result window in case the result is difficult to read.

- (3) Conditions for Testing: The following conditions must be present to use OraQuick®:

 (1) sufficient lighting to safely and accurately perform the test and read the result; (2) a level, clean surface where testing can be performed; (3) temperature of the test kit and test area shall be between 59° and 80° Fahrenheit; and (4) space that assures confidentiality for both testing and counseling.
- utilize external controls that verify whether the devices are working properly or staff are properly performing the test. Each set consists of two vials, a positive control and a negative control. The positive control (the black cap) contains a serum-based solution containing antibodies that will show a reactive result when used with the OraQuick® test. The negative control (the white cap) will show a non-reactive result when tested. If the device does not show the expected result when each control

is used, either the test was not performed properly or the device is defective.

- (a) External Kit Controls should be run under the following conditions: (1) when a staff person has been trained to conduct OraQuick® testing, prior to testing client specimens; (2) when a new box of test kits is opened at the testing site; (3) when testing conditions change: lighting, temperature, unusual environmental conditions, etc; (4) if the temperature of the test kit storage area falls outside 35°-80°F; (5) if the temperature of the testing area falls outside 59°-80°F; and (6) external controls should be conducted at least once every twenty-five (25) tests or once a month, whichever occurs first.
- (b) The external controls must be refrigerated (temperature must be between 35°-46° F). Controls do not need to be warmed to room temperature prior to use. Although the controls have an expiration date that is one year post-production, once controls are opened they <u>must</u> be used within 3 weeks. Controls shall

be dated when they are opened and discarded 3 weeks after this date. Staff may record on a refrigerator log when controls should be disposed.

- D. <u>Testing Steps</u>: The following is a summary of the steps required to complete an OraQuick® test. More detailed instructions are delineated in the OraQuick® package insert and in the Step-by-Step Instructions for OraQuick® Rapid HIV-1. Counselors must familiarize themselves with both of these resources prior to testing clients.
 - absorbent cover. Place stand, divided pouch, loops, antiseptic wipes, sterile retractable lancet, disposable gloves, sterile gauze, and bandages at workspace. Check expiration date of packet. If expired, dispose and obtain a new pouch that is not expired. Check to make sure there is an absorbent packet in the device side of the pouch. If none is present discard the entire pouch and obtain a new one. Open the two chambers of the divided pouch and label the test device and the developer solution vial with the client's project ID number. Keep the

paddle end of the device inside the package to avoid contamination. Do not cover the holes on the back of the device. Remove the cap from the vial and slide it into the stand from the top. Place the cap on the absorbent cover near the stand. Put on disposable gloves.

- (2) Collection: Clean the client's finger with an antiseptic wipe and allow it to dry thoroughly.

 Using a sterile retractable lancet, puncture the skin just off the center of the finger pad. Discard lancet in a sharps container. Allow a drop of blood to form and wipe it away with sterile gauze. Allow a second drop of blood to form and place the loop onto this drop. Make sure the blood fills the inside of the loop.
- (3) Mixing: Insert the loop into the vial being careful not to touch the loop to the sides of the vial. Stir the solution with the loop to properly mix. Discard the loop in a waste container. Make sure the solution appears pink.
- (4) Testing: Remove the device from the pouch.

 Do not touch the Flat Pad. Insert the Flat Pad end

of the device into the developing solution with the result window facing forward. Note the starting time on the testing log. Read the result of the test after 20 minutes but not more than 40 minutes from the time the device was placed in the solution.

Reading the result: A valid test result must have a reddish-purple line next to the "C" (Control) triangle. If no line is present at this area, the test is invalid and no result can be interpreted. In this case, the client must be tested again. A line at only the "C" triangle, and no line at the "T" (Test) triangle, is interpreted as a non-reactive or negative test result. client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client should be retested 3 months after the exposure. Lines at both the "C" and "T" area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen from the client to determine whether the client is infected with HIV.

- test may be invalid, staff shall review procedures to determine that the test was conducted properly. A second test shall be conducted. If this test is also invalid, external kit controls shall be run. If the expected results are not obtained, staff shall contact the appropriate project director for their site. If it appears that devices are defective, the OraSure® customer service department should be contacted at 1-800-672-7873. Testing with the OraQuick® rapid HIV-1 antibody test shall be halted until it is determined if the invalid results are due to a faulty lot of test kits.
- (7) Documentation of the Result: The OraQuick® rapid test results shall be recorded in the handheld data collection device. For individuals testing preliminary positive, contact information should be collected so that they may be re-contacted to receive a confirmatory test result. The project identification number and contact information shall be documented in a log book (see Data Collection Procedures below).

- in a sharps container and all other used test
 materials (capped vial, device, loops, used gauze
 and gloves, etc.) in a trash bag. Clean any spills
 with a surface disinfectant (EPA-registered,
 hospital grade, intermediate activity disinfectant
 such as Dispatch, Virex TB, or Cavicide). Remove
 gloves and wash hands after every test is performed.
 Use new gloves for each client.
- E. <u>Confirmatory Testing</u>: All clients receiving a reactive (Preliminary Positive) OraQuick® result should immediately have a specimen collected for a confirmatory test to determine whether they have HIV infection. All clients consenting to test, will be asked for an additional confirmatory specimen, in the event that their rapid test is preliminary positive. A serum or oral fluid specimen will be obtained from the client and sent to a laboratory for Western blot testing.
- F. <u>Disclosure of Preliminary Positive (Reactive)</u>

 Results: The following information shall be covered when providing post-test counseling to someone with a reactive OraQuick® result. Throughout this process, counselors

shall provide emotional support to assist the client to cope while waiting for the confirmatory test. The client advocates will play a crucial role in ensuring that the clients keep their scheduled confirmatory test disclosure sessions.

- (1) <u>Disclosure</u>: The test counselor will: (1) interpret the result and assess client understanding of the result; (2) explain confirmatory testing; (3) obtain commitment from client to return for confirmatory result; (4) discuss what client intends to do during waiting time, including disclosure issues; (5) encourage client to take precautions to avoid potentially transmitting the virus to others; (6) assess need for referrals; and (7) interpret the result and assess client understanding of the result. Reactive results are defined as "preliminary positives" by the Centers for Disease Control and Prevention (CDC).
- (2) <u>Confirmatory testing</u>: A specimen for confirmatory testing shall be obtained immediately for Western blot testing. If possible, a blood specimen should be drawn. If the counselor does not

perform phlebotomy, an oral fluid specimen can be obtained. Counselors shall inform clients that if the confirmatory test result were negative, a second confirmatory test, a serum test, would be done to be absolutely certain that they are not infected. Counselor shall obtain commitment from client to return for confirmatory result. Counselors shall set an appointment with the client in to receive the confirmatory test result. All confirmatory results should be provided in person to facilitate linkage to further services and provision of emotional support. Counselor shall discuss what client intends to do during waiting time, including disclosure issues. Counselors shall discuss how clients intend to cope during this waiting period and who, if anyone, they intend to tell about their rapid test result. Counselor shall encourage client to take precautions to avoid potentially transmitting the virus to others. Counselors shall encourage and support the client in use of risk reduction behaviors to avoid potentially transmitting the virus to others. This includes examining the

client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.

- (3) Assess need for referrals: At a minimum counselors shall offer to be a support to the client via phone or in person. In addition, referrals to a mental health counselor, risk reduction specialist, or crisis line shall be provided as needed by the client. A description of partner counseling and referral services, as well as access to medical care, legal services, case management, and the drug reimbursement or health insurance programs should be provided to clients testing preliminary positive.
- interpreted as negative unless the client has engaged in risk behavior within the last three months. If the client has engaged in risk behavior during this time, counselors shall recommend a retest three months after their last exposure.

 Counselors shall assess for additional services needed by the client, such as STD or hepatitis testing, alcohol and other drug abuse treatment,

economic assistance, domestic violence services, housing, etc.

- G. Disclosure of Confirmed Positive Results: The following information shall be covered when providing post-test counseling to someone with a confirmed positive HIV test result. Throughout this process, counselors shall provide emotional support to assist the client to cope with their HIV diagnosis. In addition, each site shall call upon their designated case manager or social worker to assist in the provision of positive results, who shall serve as client advocates and offer post-disclosure services that may include emotional and community support, information/assistance regarding identification and entry into medical care, PCRS services, medical and community linked referrals, and follow up.
- H. <u>Client Advocates</u>: Linking clients with appropriate medical and psychosocial referrals is a key component of this project. In order to establish a continuum of care for each client, sites will use client advocates (case managers, social workers, HIV counselors, clinicians) for each client identified as high-risk

negative or preliminary positive. Once the determination has been made that a client is high-risk negative or preliminary positive, or confirmed positive, the client advocate shall facilitate the referral process and provide follow up. The client advocate will continue to provide referrals to the client, in conjunction with an ongoing needs assessment, for appropriate referral sources and follow up. The client advocates shall work to ensure the clients keep their confirmatory test disclosure appointment. Contractor shall ensure that all linkages to care, including the sharing of referral information between agencies activities, are HIPPA compliant.

I. Linking Clients with Referral after Rapid

Testing: Through coordination with the LA County's Office of AIDS Programs, and the local network of Care providers, OAPP staff and Epidemiology Unit will be able to access the IMACS/Casewatch for client registration information, as well as clinical diagnostic measures.

Access to the IMACS/Casewatch system shall allow for collection and evaluation of post-diagnostic clinical information including patient viral load, T-cell count,

- etc. Consent to review this information will be obtained when the client enrolls in medical care services.
- Linked Referrals: Client advocates and clinic staff shall be charged with providing each willing client with linked referrals. Client advocate shall provide the client with information regarding appropriate resources and contact information for each referral source. client advocate shall assess the client's immediate need for psychosocial, medical and mental health. The client advocate shall help determine what referral services are appropriate for the clients, including referrals within the project site, or out to other local service providers. When same-day services are an option, the client advocate has three options: (1) in sites that have testing services with on-site or nearby referral services, the client advocate should walk the client to the referral source and introduce the client to the referral service provider; (2) in sites that do not have on-site referral sources, or for sites that provide rapid testing in the field, client advocates should provide transportation services for the client advocate to the referral service provider; and (3) when same-day services

are not an option for referral sources, client advocates should contact the appropriate referral service provider(s) and schedule an appointment for the client. When possible, the client advocate shall accompany the client to the scheduled appointment. If this is not possible, the client advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

K. Result of the Confirmatory HIV Test:

Confirmatory Western Blot HIV test results shall be ready within 1-2 weeks. All LA County OAPP contracted project sites will follow local protocols for reporting Western Blot HIV positive results to local and CDC surveillance. The process for providing results begins with the client's appointment for results. If the client does not make their appointment to obtain results of the confirmatory test, the client advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate shall follow the test result protocol as explained below. When the client keeps their appointment for confirmatory test results, the client advocate shall provide confirmatory

test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. In addition, the client advocate shall refer the client to medical services and reassess the client for psychosocial services. The client advocate shall determine whether or not they could obtain referral services for the client that day. If same day services are an option, the client advocate has the same three options as described. If the client does not make their appointment for referrals services, the client advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate should follow the steps outlined in the Monitoring Care Services.

L. Monitoring Care: Client advocates through each project site will work to follow up on clients to determine if they have entered medical care. OAPP staff shall work with project site staff to monitor local surveillance data to identify CD4 counts and viral load reports. This process should begin three to six months after the client's appointment for confirmatory results to allow sufficient time for the client to enter care and

for the lab reports to be entered into the surveillance system. Periodic review of IMACS/Casewatch should occur until a CD4 count and/or viral load is recorded. The client advocate shall record the appointment status (missed/kept). If the appointment was missed, the client advocate shall record the type and number of attempts to contact the client. If the appointment was kept and the lab reporting data is in the system, the client advocate shall record this data.

M. Western Blot HIV-Negative Test Result: If the client does not make their appointment to obtain results of the confirmatory test, the client advocate should follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate should follow the test result protocol. When the client keeps their appointment for confirmatory test results, the client advocate should provide negative test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the client advocate should instruct the client to return for testing in one month, due to the discordant results between the OraQuick® rapid HIV test and the Western blot.

The second Western Blot test shall be a standard serum HIV test, not an oral fluid test. In addition, the client advocate shall reassess the need for psychosocial services. The client advocate shall then determine whether or not they could obtain referral services for the client that day. If same day services are an option, the client advocate has three options as described above.

N. Western Blot Indeterminate Result: If the client does not make their appointment to obtain results of the confirmatory test, the client advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate should follow the test result protocol. When the client keeps their appointment for confirmatory test results, the client advocate shall provide indeterminate test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the Client Advocate shall recommend that the client seek additional HIV testing in one month, due to discordant results due to the discordant results between the OraQuick® rapid HIV test and the Western Blot. The second Western Blot test shall be a standard serum HIV test, not

an oral fluid test. In addition, the client advocate shall reassess the need for psychosocial services. The client advocate shall determine whether or not they could obtain referral services for the client that day. If same day services are an option, the client advocate has three options as described previously.

- 9. CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS:
 Contractor shall fully comply with the Subcontracting
 Paragraph of the ADDITIONAL PROVISIONS section of this
 Agreement. In addition, the Contractor shall ensure that
 subcontractors and consultants providing services under this
 Agreement shall commence services within ninety (90) days of
 the execution of this Agreement, or as otherwise approved by
 OAPP. Subcontract and consultant agreements shall be signed
 and dated by the Contractor's Director, or his/her
 designee(s), prior to commencement of subcontracted and/or
 consultant services.
- 10. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit:
 - A. A monthly written report together with Data

 Report no later than thirty (30) days after the end of

each calendar month. Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP. Such written monthly report and data report shall be mailed or delivered together with an invoice to Office of AIDS Programs and Policy, 600 South Commonwealth Avenue, 6th Floor, Los Angeles, California 90005, Attention: Financial Services Division.

B. Quality Assurance for the OraQuick® Rapid HIV-1
Antibody Test, Program Monitoring and Data Collection
(procedure for all clinics). LA County OAPP's Data and
Epidemiology unit provides quality assurance for all OAPP
contracted counseling and testing. This includes
provision of technical assistance, ordering and delivery
of supplies, and ordering controls. The Data and
Epidemiology unit also facilitate the collection of data
for all HCT services throughout Los Angeles County, and
will manage the data for this project. All participating
project sites will submit the client level data (PDA
data) to the Data and Epidemiology Unit for management,
centralization and dissemination. The Data and
Epidemiology unit will submit this data to CDC as

directed by their reporting and data collection schedule. In addition, LA County OAPP will conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will be asked to report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites will be incorporated into the existing monitoring schedule for all OAPP contracted programs.

ensure that its subcontractor(s) maintain adequate health records which shall be current and kept in detail consistent with good medical and professional practice in accordance with the California Code of Regulations on each individual client. Such records shall include, but shall not be limited to: the dates of the HIV risk assessment session and the disclosure session, signed consent forms for confidential tests, test results, client interviews, progress notes documenting referrals provided, and a record of services provided by the various personnel in sufficient detail to permit an evaluation

of services. The program records shall also include documentation of client demographic information and the statistical summary reports submitted monthly to OAPP. A current list of service providers for medical, psychosocial, and other referral resources shall be maintained.

Contractor shall maintain additional program records as follows: a) letters of OAPP approval for all materials utilized by the program; b) documentation of staff job descriptions, resumes, and certificates and/or letters of completion of HIV Antibody Four-Day Counselor Certification Training, One-Day Re-certification Training, Three-Day PCRS certification and re-certification training, Two-Day Rapid HIV-1 Antibody Testing certification, as well as, selected STD and HIV training as attended; and c) documentation of an annual written evaluation of employee's performance and that completed evaluation has been discussed with employee. annual evaluation shall include, but is not limited to documentation of written bi-annual observations of the counseling session, evaluation of counselor knowledge, skills and competence to provide HIV/AIDS counseling, testing and immune assessment, and referral services.

- 12. PROGRAM EVALUATION: Contractor shall assess the program's quantitative and qualitative aspects. The initial program assessment shall be conducted three (3) months following approval of this Agreement; a second assessment shall be conducted six (6) months after approval of this Agreement. The program assessments shall include:
 - A. A review of the accuracy and appropriateness of the content of the counseling sessions and the educational materials provided.
 - B. Observation and written evaluation of the counselors on a biannual basis. Notes on the counselor's performance and the feedback given to the counselor will be included in his/her employee record.

Following the assessments, the Contractor shall report to OAPP on the program's progress and any problem areas following each assessment.

13. <u>ADDITIONAL STAFFING REQUIREMENTS</u>: The Routinely recommended HIV testing in Clinical Settings using the OraQuick Rapid HIV-1 Antibody test services shall be provided by individuals who are appropriately trained, qualified, who meet the guidelines set forth by the CDC and are linguistically and culturally appropriate. All HIV testing

and disclosure counseling sessions shall be conducted by HIV Certified Counselors trained by the CDHS-OA and/or OAPP. All HIV Certified Counselors must attend an annual one-day HIV recertification training approved by OAPP.

- A. In addition to certification and recertification training, Contractor shall conduct ongoing appropriate staff training. All staff is required to obtain a minimum of 16 hours of continuing education units (CEU) per each term of this agreement in addition to the required re-certification training. The required CEU training shall include, but is not limited to, Hepatitis B and C, STDs (including chlamydia, gonorrhea and syphilis), substance abuse and PCRS training.
- B. All testing unit staff providing direct services shall attend in-service training on substance abuse knowledge, substance misuser sensitivity, cultural approaches and substance misuse related issues, as directed by OAPP under the guidelines of the State Department of Alcohol and Drug Programs.
- C. Contractor shall document training activities in the monthly report to OAPP. For the purpose of this Agreement, training documentation shall include, but are

not limited to: date, time and location of staff training; training topic(s), name of attendees and level of staff participation.

- D. All HIV Certified Counselors providing direct services shall be sensitive to the needs of persons of diverse life experiences including, substance users, persons with mental illness, transgenders, multiply-diagnosed individuals, etc.
- E. The Project Coordinator shall be appropriately trained and knowledgeable and demonstrate a high level of competency with respect to HIV/AIDS testing and counseling issues, STD and Hepatitis C Screening, substance misuse, community referrals, and education services. The Program Coordinator shall complete the CDHS-OA and/or OAPP's HIV Counselor Certification Training and/or comparable training as approved by OAPP.
- F. Staff vacancies shall be advertised in a local newspaper and/or posted at facilities throughout Los Angeles County and/or through other methods where persons with appropriate knowledge and competency can be identified. Individuals with a history of alcohol and/or drug abuse histories who are being considered for a

counselor position shall have a minimum of two (2) years sobriety.

- G. Contractor shall participate in quarterly project meetings or as directed by OAPP.
- H. Contractor shall participate in all project conference calls.
- I. Contractor shall designate one person on staff as the key person for all data collection activities related to this agreement. Said staff shall be able to represent contractor on all issues related to data collection and the evaluation thereof.

Director shall notify Contractor of any revision of these guidelines, which shall become part of this Agreement.

14. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of service(s) and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of a tuberculin skin test (Mantoux test) and/or written certification by a physician that the

person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening." Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

- approved Quality Management (QM) plan. The QM plan shall describe the process for continually assessing the contractors program effectiveness in accomplishing contractor mission, goals, and objectives. The plan shall describe the process for the following components: QM Committee, Written Policies & Procedures, Client Feedback, Program Staff, Measurable Program/Service Quality Indicators, QM Plan Implementation, and Quality Assessment & Improvement Reports.
 - A. Quality Management Committee: The QM Committee shall develop, review, and revise the agency's QM plan on an annual basis and continually assess and make recommendations for the improvement of program services. The Committee shall be responsible for developing plans of corrective action for identified program deficiencies and consist of persons that reflect the group and/or groups to whom services are targeted including clients,

volunteers, program staff, management staff, consultants, staff from other community-based organizations, etc. The Program Coordinator and a client receiving services under this contract must be included as Committee members.

Committee membership shall be described by name, title, or role, and the constituency represented (i.e., staff, management, and client). The Contractor shall review the Committee recommendations and ensure recommendations are appropriately implemented. A separate Committee need not be created if the contracted program has an established an advisory committee or the like, so long as its composition and activities conform to the criteria described in this Agreement.

The QM Committee activities shall be documented.

Required documentation shall include but not be limited to agendas, sign-in sheets, QM Committee meeting minutes (including date, time, topics discussed, recommendations, and corrective actions).

B. Written Policies and Procedures: Policies and procedures shall be based on essential program activities and community and professional standards of care specific to this contract. The QM Plan shall describe the process

for reviewing and modifying written policies and procedures. In addition, the plan shall specify the policies be reviewed at a minimum of once a year, approved and signed by the Executive Director or designee.

- C. Client Feedback: The QM Plan shall include a mechanism for obtaining ongoing feedback from program participants regarding program effectiveness, accessibility and client satisfaction. Describe the method(s) to be used for client feedback, (e.g., satisfaction surveys, focus groups, interviews, etc). Client feedback shall be collected on an ongoing basis or at a minimum of quarterly. Describe how client feedback data will be managed by the QM committee and used to make improvements to the program.
- D. Program Staff: The QM plan shall describe the process for developing, training and monitoring staff.

 This description shall include minimum qualifications for each program staff position and a description of the methods and instruments to be used to monitor staff performance. The QM plan shall specify that staff is evaluated annually.

- Ε. Measurable Program/Service Quality Indicators: Measurable quality indicators are intended to address how well services are being provided. By developing a set of indicators specific to each program, establishing a measurable minimum standard for each indicator, and conducting an assessment on the extent to which the indicator is met, the Contractor shall assess the quality of service delivery on an ongoing basis. The OM Committee is responsible for developing a plan of corrective action to address any program quality deficiencies or to improve the effectiveness demonstrated by each indicator. Quality indicators shall be based on key activities described in the SERVICES TO BE PROVIDED Paragraph of this Exhibit. The QM Plan shall require measurement of and include at a minimum the following measurable program and/or services indicators:
 - (1) Process: Eighty-five (85%) test acceptance rate for clients approached for rapid testing; eighty-five percent (85%)post-test disclosure rate; one hundred percent (100%) HIV preliminary tests completing a confirmatory test; eighty percent (80%) of clients accepting referral counseling will be

linked to appropriate levels of care services; follow-up services will be conducted for one hundred percent (100%) of clients testing preliminary positive.

- (b) Outcome: Eighty percent (80%) of clients receiving Rapid Testing services will report satisfaction with Rapid Testing services they received; seventy-five percent (75%) of clients receiving services will successfully demonstrate or discuss at least one risk reduction skill or plan.
- 16. <u>QM PLAN IMPLEMENTATION</u>: Contractor shall implement its QM plan to ensure the quality of the services provided are assessed and improved on a continuous basis.
 - A. Quality Assessment and Improvement Reports: The QM Plan shall include the requirement for two (2) Quality Assessment and Improvement Reports. These reports shall be developed by the QM Committee and signed by the Executive Director. Contractor shall make the following reports available to the OAPP Program Manager at the time of the monitoring review or upon request:

- (1) Mid-Year Report shall document program performance, results of plans of corrective action, areas of concern identified by the QM Committee, and data collected from client feedback.
- (2) Year-End Report shall document actions addressing the findings of the Mid-Year reports and the overall program performance from Mid-Year to Year-End.
- evaluation plan developed by the CDC. The pan is designed to demonstrate project accomplishments and monitor areas during the course of the project in order to improve the project's success. Evaluation measure shall include, but not be limited to: (1) number of individuals approached for rapid testing; (2) number of individuals who agree to HIV testing and other types of HIV testing; (3) number of individuals who receive rapid HIV test and confirmatory results; (4) number of HIV infected persons newly detected through rapid testing who enter into medical care; and (5) number of HIV negative persons receiving psychosocial service referrals. Contractors shall provide counseling and testing data for 2002 and 2003 for comparison purposes.

SCHEDULE 7

THE LOS ANGELES FREE CLINIC

ROUTINE HIV TESTING IN CLINICAL SETTINGS USING THE ORAQUICK RAPID HIV-ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

		Budge	et Period
	Date		Approval through 31, 2004
Salaries			\$ 56,100
Employee Benefits			\$ 12,903
Total Salaries and Employee Benefits			\$ 69,003
Operating Expenses			\$ 16,454
Capital Expenditures			\$ -0-
Other Costs			\$ -0-
Indirect Costs			\$ -0-
TOTAL PROGRAM BUDGET			\$ 85,457

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

SCHEDULE 8

THE LOS ANGELES FREE CLINIC

ROUTINE HIV TESTING IN CLINICAL SETTINGS USING THE ORAQUICK RAPID HIV-ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

	Budget	Period
	January 1 t <u>September 1</u> 4	through
Salaries	\$	93,500
Employee Benefits	\$	21,505
Total Salaries and Employee Benefits	\$ [115,005
Operating Expenses	\$	27,422
Capital Expenditures	\$	-0-
Other Costs	\$	-0-
Indirect Costs	\$	-0-
TOTAL PROGRAM BUDGET	\$ 1	142,427

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

EXHIBIT E-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV using the OraQuick Rapid HIV-1 Antibody Test as part of a Routine Medical Screening to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles

3.1 Completed materials will be kept on file and results documented in monthly reports to OAPP.	5/18/04 and ongoing	3.1 Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	3.0 By 12/31/04, 100% of clients completing a Rapid Test will receive disclosure services.	3.0
2.3 Completed materials will be kept on file and results documented in monthly reports to OAPP.	5/18/04 and ongoing	2.3 Administer rapid HIV test. Document test results on PDA. Submit findings to OAPP.		
22 Letter(s) of OAPP approval and related material will be kept on file.	By 6/18/04	2.2 Administer consent form, medical release form, and disclaimer. Complete client logs.		
2.1 Completed materials will be kept on file and results documented in monthly reports to OAPP.	5/18/04 and ongoing	2.1 Develop consent forms, medical release forms, disclaimers and client logs. Submit materials to OAPP for approval.	2.0 By 12/31/04, a minimum of 372 (85%) patients who accept services will receive Rapid HIV testing.	2.0
1.3 Completed materials will be kept on file and results documented in monthly reports to OAPP.	5/18/04 and ongoing	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.		
1.2 Calendar will be kept on file and submitted with monthly reports to OAPP.	5/18/04 1 and ongoing	1.2 Schedule HCT activities and maintain calendar of sites, dates, and times.		
		conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	Rapid HIV test.	
I.1 Letter(s) of OAPP approval and related material will be kept on file.	By 6/18/04 1	1.1 Develop Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for	uinimum of 438 patients will sk assessments and be offered a	1.0
METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION	TIMELINE	IMPLEMENTATION ACTIVITIES	MEASURABLE OBJECTIVE(S)	
			ounty.	County.



EXHIBIT E-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV using the OraQuick Rapid HIV-1 Antibody Test as part of a Routine Medical Screening to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

3.1 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	3.1 Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	By 12/31/05, 100% of clients completing a Rapid Test will receive disclosure services.	3.0
2.3 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	2.3 Administer rapid HIV test. Document test results on PDA. Submit findings to OAPP.		
22 Letter(s) of OAPP approval and related material will be kept on file.	1/1/05 and ongoing	2.2 Administer consent form, medical release form, and disclaimer. Complete client logs.		
2.1 Completed materials will be kept on file and results documented in monthly reports to OAPP.	Ву 2/1/05	2.1 Review and revise, as needed, consent forms, medical release forms, disclaimers and client logs. Submit materials to OAPP for approval.	By 12/31/05, a minimum of 637 (85%) patients who accept services will receive Rapid HIV testing.	2.0
1.3 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.		
1.2 Calendar will be kept on file and submitted with monthly reports to OAPP.	1/1/05 and ongoing	1.2 Schedule HCT activities and maintain calendar of sites, dates, and times.		
1.1 Letter(s) of OAPP approval and related material will be kept on file.	By 2/1/05	1.1 Review and revise, as needed, Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	1.0 By 12/31/05, a minimum of 750 patients will receive a brief risk assessments and be offered a Rapid HIV test.	1.0
METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION	TIMELINE	IMPLEMENTATION ACTIVITIES	MEASURABLE OBJECTIVE(S)	



HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) HEALTH EDUCATION/RISK REDUCTION PREVENTION SERVICES AGREEMENT

Amendment No. 2

	THIS AMENDMENT	is made and entered into this day
of _		, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	CHILDRENS HOSPITAL LOS ANGELES (hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) HEALTH EDUCATION/RISK REDUCTION PREVENTION SERVICES AGREEMENT", dated December 12, 2000, and further identified as Agreement No. H-212033, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and provide other changes set forth herein; and

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor will participate in the Los Angeles County Eligible Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, where there is a Service Provider Network (SPN) in the SPA in which Contractor provides services, Contractor's

active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor must implement a "consumer advisory committee" with regular meetings and consumer membership as a mechanism for continuously assessing client need and adequacy of Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor must actively collaborate and recruit referrals from service organizations and agencies beyond the Ryan White CARE Act service delivery system, including, but not limited to, substance abuse, mental health, primary health care and social services organizations.

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor's referrals to and from organizations must be noted and tracked in the OAPP service utilization data system, and followed up in client need and adequacy of Contractor's services, and to obtain client feedback.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on January 1, 2001 and continue in full force and effect through December 31, 2004. Said Agreement shall thereafter be automatically renewed for two (2) twelve (12) month terms, effective January 1, 2005 through December 31, 2005, and January 1, 2006 through December 31, 2006 and a one (1) eight (8) month term, effective January 1, 2007 through August 31, 2007, subject to the availability of federal, State, or County funding sources. If such funding sources are not forthcoming, this Agreement shall terminate December 31, 2004. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."
- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:

- "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, A-1, A-2, A-3, B, B-1, B-2, B-3, B-4, B-5, B-6, E, E-1, E-2, E-3, E-4, E-5 E-6, and F, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>, Subparagraph F, G, H and I, shall be added to Agreement as follows:
 - "F. During the period date of Board approval through December 31, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Two Hundred Fifty-Four Thousand, Sixty Dollars (\$254,060). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 16, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.
 - G. During the period January 1, 2005 through December 31, 2005, the maximum obligation of County for all services provided hereunder shall not exceed One Hundred Eighty-Five Thousand, One Hundred Eighty-One Dollars (\$185,181). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of

National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 17, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.

- H. During the period January 1, 2006 through December 31, 2006, the maximum obligation of County for all services provided hereunder shall not exceed One Hundred Sixty-Five Thousand, Fifty-Five Dollars (\$165,055). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 18, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.
- I. During the period January 1, 2007 through August 31, 2007, the maximum obligation of County for all services provided hereunder shall not exceed Eighty-Nine Thousand, One Hundred Seventy-Nine Dollars (\$89,179). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total

maximum obligation of County as shown in Schedule 19, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services."

- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder for actual

 reimbursable net cost basis as set forth in Schedules 1, 2,

 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, and

 19, and the <u>COST REIMBURSEMENT</u> Paragraph of this Agreement."
- 6. EXHIBIT F, SCOPE OF WORK FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE, PREVENTION WITH POSITIVES SERVICES, are attached to this Amendment and incorporated in this Agreement by reference.
- 7. Schedules 16, 17, 18, and 19, BUDGETS FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE, PREVENTION WITH POSITIVES SERVICES, are attached to this Amendment and incorporated in this Agreement by reference.
- 8. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

Director of Health Services, and Contractor has caused this

Amendment to be subscribed in its behalf by its duly authorized
officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

Ву	
	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
CH:	ILDRENS HOSPITAL LOS ANGELES
	Contractor
Ву	
_	Signature
	Printed Name
Tit	ile
	(AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

DEPARTMENT OF HEALTH SERVICES

APPROVED AS TO CONTRACT ADMINISTRATION:

By ______ Irene E. Riley, Director Contract Administration

EXHIBIT F

CHILDRENS HOSPITAL OF LOS ANGELES

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS)
PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED
PERSONS SEEN IN PRIMARY CARE SETTINGS
(PREVENTION WITH POSITIVES)

1. DEFINITIONS:

- A. Immune deficiency caused by the Human

 Immunodeficiency Virus (HIV) is a spectrum of disease which

 ranges from asymptomatic HIV disease to Acquired Immune

 Deficiency Syndrome (AIDS) as defined by the Federal Centers

 for Disease Control and Prevention (CDC).
- B. The U.S. Health Resources and Services

 Administration (HRSA) funds Special Projects of National

 Significance (SPNS) to explore HIV/AIDS care and treatment

 best practices, innovative service methods and system

 improvements. In 2003, HRSA launched a SPNS initiative

 seeking new projects to demonstrate the effectiveness of

 prevention education for people with HIV/AIDS in primary

 health care settings. Los Angeles County's Office of AIDS

 Programs and Policy (OAPP) received one of 15 SPNS

 Prevention with Positives grant awards nationwide.
- C. "Prevention with Positives" encompasses the spectrum of prevention education activities targeting people

who are HIV-positive. Providing prevention education and eliciting the involvement of HIV-positive people in the effort to stem the HIV infection rate is a key priority of the U.S. Centers for Disease Control (CDC). Prevention with Positives activities can take place in a variety of settings; the SPNS initiative focuses on the primary health care setting.

HRSA defines Prevention with Positives activities directed by the primary providers (e.g., physicians, nurses, etc.) as "provider-based", and those activities directed by others at service sites as "specialist-based". The OAPP demonstration project uses the "provider-based" model.

D. "Intervention" describes the proposed "prevention for positive" education that to be used in the new demonstration model. "Evaluation" defines those activities conducted to measure the effectiveness of the intervention. Those clinics incorporating the intervention into their regular, ongoing medical visits and participating in the evaluation are "intervention sites". The clinic not using the intervention, but participating in the evaluation is the "control site."

2. <u>PERSONS TO BE SERVED</u>: All HIV-positive clients receiving medical services at contracted intervention sites will be given Prevention with Positives education during their medical appointments, in accordance with directions from the project training and as described hereunder in following sections.

All contracted clinics will be required to help project evaluators identify a minimum of 150 medical clients for participation in evaluation activities, as described hereunder in following sections.

3. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period of date of Board approval through August 31, 2007, that portion of County's maximum obligation which is allocated under this Exhibit for participation in the SPNS-funded Prevention with Positives Demonstration Project shall not exceed Six Hundred Ninety-Three Thousand, Four Hundred Seventy-Five Dollars (\$693,475).

4. COMPENSATION:

A. County agrees to compensate Contractor for allowable reimbursable costs associated with participation in the SPNS-funded Prevention with Positives Demonstration Project, in accordance with the budgets set forth in Schedules 16, 17, 18, and 19, attached hereto and incorporated herein by reference, as the budgetary items

currently exist or as they are modified in the future by the Office of AIDS Programs and Policy (OAPP).

- B. Payment for services provided hereunder shall be subject to the provisions set forth in the REPORTS Paragraph of this Agreement.
- 5. <u>CLIENT/PATIENT ELIGIBILITY</u>: Contractor shall ensure that HIV infection is confirmed for all clients by an accepted laboratory diagnostic test. Such confirmation shall be documented in each client's medical record.
- 6. SERVICE DELIVERY SITE(S): During the period of this Agreement, Contractor's facility where participation in the demonstration project will be headquartered is located at: 5000 Sunset Boulevard, Los Angeles, California 90027.

 Training/consultation services provided in accordance with subcontract will be headquartered at 1441 East Lake, MS-9175, Los Angeles, CA 90033. Subcontracted intervention site participation will be located at 1000 W. Carson St, Bldg N-24, Torrance, CA 90509.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before moving location(s) of demonstration project participation.

- 7. SERVICES TO BE PROVIDED/SCOPE OF WORK: During the term of this Agreement, Contractor shall serve as the primary evaluator of demonstration project activities. Contractor will also subcontract with two organizational partners providing training/consultation services and participating as one of the intervention sites.
 - A. Evaluation: Contractor shall lead the evaluation effort in the demonstration project, entailing the following activities:
 - (1) Develop, design and produce demonstration project data collection instruments;
 - (2) Serve as the primary representative to the Enhancing Prevention with Positives Evaluation Center (EPPEC) at University of California San Francisco (UCSF) on multi-site evaluation activities;
 - (3) Develop and submit annual Insitutional
 Review Board (IRB) applications and reports in
 accordance with all IRB requirements imposed on the
 demonstration project, and serve as lead respondent to
 IRB queries and recommendations.

- (4) Conduct all client baseline and six-month, 12-month and 18-month follow-up interviews at intervention and control sites;
- (5) Conduct qualitative interviews throughout the project with provider staff and clients, as determined by project management team;
- (6) Enter all data collected from clients and providers accurately and consistently on designated data management system, and submit required data to EPPEC in accordance with project requirements;
- (7) Certify validity and accuracy of data on a regular basis;
- (8) Lead and/or participate in the lead of focus group and Consumer Advisory Board (CAB) meetings, as needed and appropriate;
- (9) Compile, assess and analyze data and findings when interviews are complete;
- (10) Lead and/or participate in the development of written, verbal and other forms of information summary, monographs and presentations on the project, and helping to disseminate findings to a wide audience locally and nationally;

- (11) Comply with all relevant IRB, HIPAA, national and local data collection, evaluation, research and study standards;
- (12) Participate as a key member of the project management team and attending project-related meetings and conference calls, as appropriate and needed.
- B. <u>Training and Consultation</u>: Contractor shall subcontract with Jean Richardson, Dr.P.H., at USC School of Preventive Medicine to provide the following services:
 - (1) Provide initial, "booster"(follow-up), and replacement trainings to the two intervention sites within the first project year;
 - (2) Provide initial, "booster"(follow-up), and replacement trainings to the control site at the conclusion of the evaluation, in the third year;
 - (3) Coordinate individual arrangements for the trainings with the respective providers,
 - (4) Modify, revise and adapt existing curricula for the trainings;
 - (5) Develop all materials for use in the trainings and as supplementary prevention education in the primary care settings;

- (6) Help detail and enumerate methods and protocols to ensure that intervention sites effectively and consistently (Quality Assurance);
- (7) Consult and collaborate on the development of assessment and evaluation instruments;
- (8) Provide expert advise and consultation to the evaluation team during the data collection, statistical and evaluation analysis phases of the demonstration project;
- (9) Lead and/or participate in the development of written, verbal and other forms of information summary, monographs and presentations on the project, and helping to disseminate findings to a wide audience locally and nationally;
- (10) Participate as a key member of the project management team and attending project-related meetings and conference calls, as appropriate and needed.
- C. <u>Intervention Site</u>: Contractor shall subcontract with Research Education Institute (REI) associated with Los Angeles County Harbor-UCLA Medical Center for participation as an intervention site in the demonstration project. All provider sites will, from time to time, be required to

participate in project-related meetings and/or other events, as appropriate and necessary. Participating as an intervention site entails the following services and activities:

- (1) Trainings: All relevant clinical staff will sit for a) an initial one-half to one-day training detailing implementation of the proposed Prevention with Positives intervention, b) a "booster" (follow-up) training approximately a month later, and c) any "replacement" trainings necessitated and as appropriate. Contractor will provide the space for the trainings; OAPP will provide all other logistical arrangements. Trainings are expected to be completed by the project's first year.
- (2) <u>Interventions</u>: Contractor shall participate in the implementation of project intervention, to include, but not limited to:
 - (a) Integration and on-going usage of prevention education/counseling messages, as detailed in the trainings, with proper consistency and at correct dosages, in the standard medical appointment with all clients;

- (b) Use of certain materials in the intervention, such as the prescription pad and Sexual Health Assessment (SHA), designed in collaboration with the Contractor;
- (c) Posting and disseminating project prevention education materials as appropriate for clients and preceding counseling during medical appointments, as and where appropriate in the primary care setting, and in accordance with clinic operational procedures;
- (d) In compliance with quality management obligations outlined in this Agreement, Contractor will ensure ongoing quality assurance efforts to confirm providers' usage of the client-level interventions in accordance with existing project concept and design methodology.

Contractor shall use the interventions for up two project years, starting in the first project year. Contractor is free to adapt the intervention to its specific needs at the conclusion of the project intervention phase.

- (3) <u>Evaluation</u>: Contractor shall participate in all project evaluation activities, to include, but not limited to:
 - (a) Referring appropriate clients to interviewers for recruitment into the project evaluation;
 - (b) Providing adequate, private, secure
 space for interviewing and data entry, and storage
 (if required by Contractor);
 - (c) Facilitating Institutional Review Board
 (IRB) process if required specifically for the
 Contractor;
 - (d) Assisting with the screening and securing client consents when and wherever appropriate and possible;
 - (e) Preparing and adhering to charting, documentation and other operational procedures as outlined in the project design;
 - (f) Providing appropriate documentation when and where needed as required to support evaluation, data entry and subsequent analysis;

- (g) Coordinating the recruitment of Contractor personnel to participate in qualitative provider interviews;
- (h) Helping to recruit clients to participate in project focus group activities, as needed and appropriate.

Intervention site participation in the project evaluation is a three-year effort and will begin in the latter half of the project's first year.

- 8. CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS:

 Contractor shall ensure that subcontractors and consultants

 providing services under this Agreement shall commence services

 within thirty (90) days of the execution of the subcontracting

 agreements. Subcontract and consultant agreements shall be

 signed and dated by the Contractor's Director, or his/her

 authorized designee(s) prior to commencement of subcontracted

 and/or consultant services.
- 9. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following report(s):

- A. Monthly Report: Contractor shall submit to OAPP a monthly report together with an invoice no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP.
- B. <u>Semi-Annual</u>: Contractor shall submit to OAPP a semi-annual report within the time period as directed for each six month period. Semi-annual reports shall include all the required information and be completed in the correct format.
- C. Annual Report: Contractor shall submit to OAPP an annual report within the time period as directed for each year. Annual reports shall include all the required information and be completed in the correct format.
- 10. QUALITY MANAGEMENT: Contractor shall implement a Quality Management (QM) program that assesses the extent to which the care and services provided are consistent with Federal (e.g., Public Health Services and CDC Guidelines), state, and local standards of HIV/AIDS care and services.

The QM program shall at a mimimum: 1) Identify leadership and accountability of the medical director or executive director, 2)

Use measurable outcomes and data collected to determine progress

toward established benchmarks, 3) Focus on linkages to care and support services and client perception pertaining to their health and the effectiveness of the service received, 4) Be a continuous quality improvement (CQI) process reported to senior leadership annually.

A. Quality Management Plan: Contractor shall base its program on a written QM plan. Contractor shall develop one agency-wide QM plan that encompasses all HIV/AIDS care and prevention services if possible. The QM plan is to be submitted to OAPP at the beginning of a contract term. The plan shall be reviewed and updated annually by agency's QM committee and signed by the medical director or executive director. QM plan and program, will be reviewed by OAPP staff during the QM program review.

The written Quality Management plan shall at a minium include the following components:

- 1) Objectives: QM plan should delineate specific goals and objectives that are in line with the program's mission, vision and values.
- 2) <u>OM Committee</u>: Describes the purpose of the committee, composition, meeting frequency, at a minimum quarterly, and required documentation (e.g., minutes,

agenda, sign-in sheet, etc.). A separate Committee need not be created if the contracted program has established an advisory committee or the like, so long as its composition and activities conform to the QM program objectives.

3) <u>Selection of a QM Approach</u>: Describes the QM approach, such as Plan-Do-Study-Act (PDSA), Chronic Care Model or Joint Commission on Accreditation of Healthcare Organization (JCAHO) 10-Step model, etc.

4) OM Program Content:

- a. Measurement of Outcome Indicators at a minimum, collection and analysis of data measured from the specific OAPP selected indicators. In addition, contractor can measure other aspects of care and services as needed.
- b. Development of Data Collection Method to include sampling strategy (e.g., frequency,
 percentage of sample size), collection method
 (e.g., chart abstraction, interviews, surveys,
 etc.), and creation of a data collection tool.
- c. Collection and Analysis of Data results to be reviewed and discussed by the QM committee.

The findings of the data analysis are to be communicated with all program staff involved.

- d. Identify and Sustain Improvement QM committee shall be responsible for identifying improvement strategies, tracking progress, and sustaining the improvement achieved.
- 5) Random Chart Audits (Medical Outpatient,
 Medical Nutrition, Case Management, Mental Health,
 Psychiatry, and Dental Providers of Care Services):
 Sampling criteria shall be based on important aspects
 of care and shall be, at a minimum, 10% or 30 charts,
 whichever is less. Results of sampling to be reported
 and discussed in the QM committee quarterly.
- describe the mechanism for obtaining ongoing feedback regarding service effectiveness, efficacy, accessibility, and satisfaction. Client input obtained shall be discussed at the QM Committee on a regular basis for the enhancement of the service delivery. Aggregated data is to be reported to the QM committee annually for continuous program improvement.

- 7) Client Grievance Process: Contractor shall establish policy and procedure for addressing and resolving client's grievances at the level closest to the source within agency. The grievance data is to be tracked, trended, and reported to the QM committee for improvements of care and services. The information is to be made available to QM staff during program reviews.
- B. Quality Management Program: To determine the compliant level, OAPP shall review contractor's QM program annually. A numerical score will be issued to the contractor's QM program based on 100% as the maximum score. Contractor's QM program shall be assessed for implementation of the following components:

OM Program Objectives

QM Committee

Selection of a QM Approach

QM Program Content

Random Chart Audit (if applicable

Client Feedback Process

Client Grievance Process

SCHEDULE 16

CHILDRENS HOSPITAL OF LOS ANGELES

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	<u>Budget</u>	<u>Period</u>
Date	of Board A	pproval
		through
	December 3	1, 2004
Salaries	\$	102,957
Employee Benefits	\$	21,483
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$	124,440
Operational Expenses	\$	29,096
Subcontract/Training and Consultation	\$	59,000
Subcontract/Intervention Site	\$	26,250
Indirect Cost	\$	15,274
TOTAL PROGRAM BUDGET	\$	254,060

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

SCHEDULE 17

CHILDRENS HOSPITAL OF LOS ANGELES

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period January 1, 2005 through December 31, 2005
Salaries	\$ 82,027
Employee Benefits	\$ 16,927
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 98,324
Operational Expenses	\$ 20,106
Subcontract/Training and Consultation	\$ 20,075
Subcontract/Intervention Site	\$ 35,000
Indirect Cost	\$ 11,676
TOTAL PROGRAM BUDGET	\$ 185,181

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

SCHEDULE 18

CHILDRENS HOSPITAL OF LOS ANGELES

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period January 1, 2006 through December 31, 2006
Salaries	\$ 59,608
Employee Benefits	\$ 12,893
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 72,501
Operational Expenses	\$ 7,487
Subcontract/Training and Consultation	\$ 41,805
Subcontract Intervention Site	\$ 35,000
Indirect Cost	\$ 8,262
TOTAL PROGRAM BUDGET	\$ 165,055

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

SCHEDULE 19

CHILDRENS HOSPITAL OF LOS ANGELES

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	January	through
Salaries	\$	27,106
Employee Benefits	\$	6,418
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$	33,524
Operational Expenses	\$	4,362
Subcontract/Training Consultation	\$	21,239
Subcontract/Intervention Site	\$	26,250
Indirect Cost	\$	3,804
TOTAL PROGRAM BUDGET	\$	89,179

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) PREVENTION SERVICES FOR HIV INFECTED PERSONS SERVICES AGREEMENT

Amendment No. 3

	THIS AMENDMENT	is made and entered into this day
of _		, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	AIDS HEALTHCARE FOUNDATION (hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) PREVENTION SERVICES FOR HIV INFECTED PERSONS SERVICES AGREEMENT", dated November 14, 2000, and further identified as Agreement No. H-207279, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and provide the changes set forth herein; and

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor will participate in the Los Angeles County Eligible Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of State and/or federal Centers for Disease Control and Prevention (CDC) funds, where there is a Service Provider Network (SPN) in the SPA in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must implement a "consumer advisory committee" with

regular meetings and consumer membership as a mechanism for

continuously assessing client need and adequacy of

Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must actively collaborate and recruit referrals

from service organizations and agencies beyond the Ryan White

CARE Act service delivery system, including, but not limited

to, substance abuse, mental health, primary health care and

social services organizations.

WHEREAS, as a recipient of State and/or CDC funds,
Contractor's referrals to and from organizations must be noted
and tracked in the OAPP service utilization data system, and
followed up in client need and adequacy of Contractor's
services, and to obtain client feedback.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties hereto agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on November 14, 2000 and continue through December 31, 2004. Said Agreement shall thereafter be renewed for a nine (9) month and two (2) week term effective January 1, 2005 through September 14, 2005 subject to the availability of Federal, State or County funds. If such funding is not forthcoming, this agreement shall terminate on December 31, 2004. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. In any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, A-1, D, D-1, D-2 E, E-1, F, F-1 and F-2, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>,

 Subparagraphs E and F, shall be added to Agreement as follows:
 - "E. During the period date of Board approval through December 31, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Ninety-Nine Thousand, Four Hundred Eighty-Seven Dollars (\$99,487). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 5, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative Partner Counseling and Referral with HIV Testing Services.
 - F. During the period January 1, 2005 through
 September 14, 2005, the maximum obligation of County for
 all services provided hereunder shall not exceed One
 Hundred Sixty-Five Thousand, Eight Hundred Thirteen

Dollars (\$165,813). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 6, attached hereto and incorporated herein by reference.

Such funds shall be used entirely for the Advancing HIV Prevention Initiative Partner Counseling and Referral with HIV Testing Services."

- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder for actual
 reimbursable net cost basis as set forth in Schedules 1,

 2, 3, 4, 5 and 6, and the <u>COST REIMBURSEMENT</u> Paragraph of
 this Agreement."
- 6. Paragraph 16, <u>HEALTH INSURANCE PORTABILITY AND</u>

 <u>ACCOUNTABILITY ACT OF 1996</u>: shall be added to Agreement as follows:
 - "16. <u>HEALTH INSURANCE PORTABILITY AND</u>

ACCOUNTABILITY ACT OF 1996: The parties acknowledge the existence of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"). Contractor understands and agrees that as a provider of medical treatment services, it is a

"covered entity" under HIPAA and, as such, has obligations with respect to the confidentiality, privacy and security of patients' medical information, and must take certain steps to preserve the confidentiality of this information, both internally and externally, including the training of its staff and the establishment of proper procedures for the release of such information, and the use of appropriate consents and authorizations specified under HIPAA.

The parties acknowledge their separate and independent obligations with respect to HIPAA, and that such obligations relate to transactions and code sets, privacy, and security. Contractor understands and agrees that it is separately and independently responsible for compliance with HIPAA in all these areas and that County has not undertaken any responsibility for compliance on Contractor's behalf. Contractor has not relied, and will not in any way rely, on County for legal advice or other representations with respect to Contractor's obligations under HIPAA, but will independently seek its own counsel and take the necessary measures to comply with the law and its implementing regulations.

Contractor and County understand and agree that each is independently responsible for HIPAA compliance and agree to take all necessary and reasonable actions to comply with the requirements of the HIPAA law and implementing regulations related to transactions and code set, privacy, and security. Each party further agrees to indemnify and hold harmless the other party (including their officers, employees, and agents), for its failure to comply with HIPAA."

- 7. Exhibits F, F-1, and F-2, SCOPES OF WORK FOR HIV/AIDS PREVENTION FOR HIV INFECTED PERSONS PARTNER COUNSELING AND REFERRAL WITH HIV TESTING SERVICES, are attached hereto and incorporated herein by reference.
- 8. Schedules 5 and 6, BUDGETS FOR HIV/AIDS PREVENTION FOR HIV INFECTED PERSONS PARTNER COUNSELING AND REFERRAL WITH HIV TESTING SERVICES, are attached hereto and incorporated herein by reference.
- 9. Except for the changes set forth hereinabove,
 Agreement shall not be changed in any respect by this
 Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COU	JNTY	OF LOS	S ANGELES
Ву			
	Dir		Garthwaite, M.D. and Chief Medical
AII	OS H	EALTHC	ARE FOUNDATION
			Contractor
Ву			,
-			Signature
			Printed Name
Tit	le		
		(AFFIX	CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

DEPARTMENT OF HEALTH SERVICES

APPROVED AS TO CONTRACT ADMINISTRATION:

Irene E. Riley, Director
Contract Administration

EXHIBIT F

AIDS HEALTHCARE FOUNDATION

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES AGREEMENT

1. DEFINITION: Partner counseling and referral services (PCRS) with HIV testing using the OraQuick Rapid HIV-1 antibody test services provide PCRS to HIV-positive individuals; HIV testing services to identified sex or injection drug use partners; pre- and post-test counseling for HIV antibodies; referrals to appropriate health and social services as needed by client; and the provision of appropriate HIV risk reduction intervention based on client's need. Such services shall be provided through clinics, health facilities, or non-clinic based community services providers. For the purposes of this Agreement, a linked referral is any referral that is facilitated by the providers and confirmed as met by the referring agency. At a minimum, a linked referral must include: referral information provided in writing and verification regarding client's access to services. Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services are provided free of charge and on confidential basis.

- 2. PERSONS TO BE SERVED: PCRS services shall be provided to HIV-positive individuals whose diagnosis has been reported to the state/local health department. HIV testing using the OraQuick Rapid HIV-1 antibody test services shall be provided to identified sex or injection drug use partners that meet the following criteria: (1) are at least 12 years of age, (2) are not previously known to be HIV infected, (3) are residents of Los Angeles County, (4) are without unstable psychiatric condition, (5) are not under the influence of alcohol or other illicit drug, and (6) are not identified as a prisoner or detainee in Service Planning Areas (SPAs) 1, 2, 3, 4, 5, 6, 7, or 8 of Los Angeles County.
- 3. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period date of Board approval, through September 14, 2005, that portion of County's maximum obligation which is allocated under this Exhibit for PCRS with HIV testing using the OraQuick Rapid HIV-1 antibody test services shall not exceed Two Hundred Sixty-Five Thousand, Three Hundred Dollars (\$265,300).
- 4. <u>COMPENSATION</u>: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedules 5 and 6. Payment for services provided hereunder shall be subject to the provisions set forth in the <u>COST REIMBURSEMENT</u> Paragraph of this Agreement.

5. <u>SERVICE DELIVERY SITE(S)</u>: Contractor's facilities where services are to be provided hereunder are located at:
6255 West Sunset Boulevard, Los Angeles, California 90028;
6210 Sunset Boulevard, Los Angeles, California 90028;
1414 South 44758 Elm Avenue, Lancaster, California 93534, and other sites as approved by OAPP's Director.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before terminating services at such location(s) and/or before commencing such services at any other location(s). OAPP reserves the right to approve and deny all requests and will make such decisions based on the appropriateness of the request.

6. SERVICES TO BE PROVIDED: During each term of this Agreement, Contractor shall provide PCRS with HIV testing using the OraQuick Rapid HIV-1 antibody test to persons meeting the eligibility criteria, in accordance with procedures formulated and adopted by Contractor's staff, the Centers for Disease Control and Prevention (CDC); consistent with California law; California Department of Health Services (CDHS) - Office of AIDS (OA) guidelines and the terms of this Agreement. The Director of OAPP shall notify Contractor of any revisions to OAPP policies and procedures, which shall become part of this Agreement. Pre-test and disclosure

counseling shall follow Los Angeles County guidelines for HIV Prevention Counseling as adopted by the Centers for Disease Control and Prevention (CDC) and CDHS-OA. All counseling sessions shall take place in a private, face-to-face session in closed room or area that ensures patient confidentiality. All PCRS shall follow the CDC guidance on HIV PCRS. Additionally, Contractor shall provide such services as described in Exhibits F, F-1 and F-2, Scopes of Work, attached hereto and incorporated herein by reference.

Minimum services to be provided shall include, but not be limited to, the following:

- A. Provide PCRS to at least 80% of newly diagnosed HIV-positive persons upon acceptance by client.

 Individuals who do not wish to receive PCRS will be asked for their age, gender, race and reasons for refusal so that characteristics of non-respondents can be evaluated.
- B. Provide Confidential testing upon acceptance by client. Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. For those clients who wish to only be tested anonymously, a referral to an anonymous HCT site will be provided.

Provide a client-centered counseling session that engages the client in a dialogue that encourages the disclosure of unique individual needs and concerns related to HIV risk and emphasizes personal options that limit or prevent transmission of HIV. During the session the counselor should also explain the differences and methods of standard testing (serum and/or oral fluid) and OraQuick testing, the procedures related to each of the testing options, and any relevant information regarding the "window period." Additionally, the client-centered counseling session should accomplish the following: a) improve the client's self-perception of risk; b) support behavior change previously accomplished or attempted by the client; c) negotiate a workable short-term and longterm risk reduction plan based on the client's perceived ability to change his or her behavior; d) support informed decision-making about whether to be tested; e) obtain informed consent; f) obtain consent to draw a confirmatory test specimen in the event the rapid test result is preliminary positive; g) review the nexus between HIV and STD infections; h) ensure that the client understands the meaning of test results, including a reactive OraQuick result requiring confirmatory testing;

- and i) assess the client's potential reaction to receiving a reactive rapid test. The Contractor shall fully collect client demographic information using the handheld computer system using iPAQ Pocket Personal Computers provided by OAPP. All information reported on the approved device(s) and lab slips shall be voluntarily supplied by the client.
- 7. Provide an FDA-approved Rapid HIV-1 antibody test to determine the presence of HIV antibodies. The provision of screening procedures shall be preceded by a review with the client of the following areas: a) information regarding risks and benefits of the Rapid HIV-1 antibody test; b) an explanation of the meaning of the respective test results; c) an explanation of the respective testing procedures; d) information on the importance of a confirmatory test if the test result is preliminary positive; e) a review of the HIV-antibody window period; and f) completion of OAPP-approved consent form signed by the client and maintained in the client's file in accordance with the California Code of Regulations.
 - A. The HIV Certified Counselor shall ensure to follow the steps to testing using the OraQuick Rapid HIV- 1 Antibody test as delineated in the OraQuick package

insert and in the Step-by-Step Instructions for OraQuick Rapid HIV-1 Antibody Test.

- B. Conduct a client-centered disclosure counseling session that serves to provide the client with their results and that integrates the test result in a meaningful and productive manner based on their reported risk factors and consistent with their risk reduction efforts. Test results shall not be mailed, nor disclosed over the phone, nor given to anyone except the client, nor given in the presence of other persons with the exceptions stipulated by California Health and Safety Codes 121010, 121015, 121020, 120975, 120980, and 120985.
- C. The HIV Certified Counselor reviewing the client's Counseling Information shall precede the disclosure session. The HIV Certified Counselor personalizing and framing the session to the client to establish a comfortable setting by describing disclosure session steps shall precede the disclosure event. The HIV Certified Counselor shall disclose the results, review the medical interpretation of the test result and assess the client's emotional state, counseling needs, understanding of the test results, need to be re-tested based on the window period and recent risk behaviors, and

need for a confirmatory test for preliminary positive results. The HIV Certified Counselor shall assess the client's understanding of and commitment to risk reduction guidelines as well as the strength of social support and plans for and consequences of disclosure to others.

D. For clients testing HIV-positive, the following additional topics shall be covered in the disclosure session; a) information regarding the confirmatory test when test results are preliminary positive; b) information regarding the risk of HIV transmission to the fetus or newborn during pregnancy, during labor and delivery, and during the postpartum period if the individual is a woman or the male partner of a women of childbearing age; c) information on the risks of reinfection; e) written documentation of information and/or assistance with partner notification and/or linkage to Los Angeles County Department of Health Services Partner Counseling Referral Services (PCRS) and field follow-up services for assisted partner notification; and e) a written assessment of the client's reaction to the positive test result to determine whether referral for

psychosocial support services, including suicide prevention, is indicated.

- The HIV Certified Counselor shall assess the need for referrals and provide specific, written referrals with adequate linkages as appropriate. At a minimum, referrals to the following services shall be considered based on client risk and test results: risk reduction, prevention for HIV-infected persons, mental health counseling, partner counseling and referral services, and tuberculosis screening and drug treatment services. For HIV-positive clients written referrals to a minimum of three (3) primary medical care providers shall be provided and any other linked referrals appropriate to the immediate health and social needs of the client. The Contractor shall document all linked referrals and referral follow-up for each person served under this Agreement. The linked referral follow-up shall include, but not be limited to, the agency the person was referred to, any appointment(s) made, no show for said appointment, and follow-up plan, if the individual failed to show for confidential testing.
- F. Contractor shall comply with the Interim

 Revision of Requirements for Content of AIDS-related

Written Materials, Pictorials, Audiovisuals,

Questionnaires, Survey Instruments, and Educational
Sessions in Centers for Disease Control Assistance

Programs, as referenced in Exhibit B.

- G. Contractor shall obtain written approval from OAPP's Director for all educational materials utilized in association with this Agreement prior to its implementation.
- H. Contractor shall submit for approval such educational materials to OAPP at least thirty (30) days prior to the projected date of implementation. For the purposes of this Agreement, educational materials may include, but not limited to, written materials (e.g., curricula, pamphlets, brochures, fliers), audiovisual materials (e.g., films, videotapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings).
- I. Failure of Contractor to abide by this requirement may result in the suspension of this Agreement at the Director's sole discretion.
- J. Contractor shall utilize funds received from County for the sole purpose of providing HIV/AIDS

counseling, testing, immune assessment, and referral services.

- K. Contractor shall not utilize funds received from County for the purpose of any and all activities associated with needle exchange, including, but not limited to, purchasing and exchanging of needles.
- L. Contractor shall ensure that all staff supported by County funds are not engaged in any and all needle exchange activities.
- M. Contractor shall be responsible for reimbursing County for all funds expended on any and all activities associated with needle exchange.
- N. Any breach of these provisions shall result in the immediate termination of agreement.

8. ADDITIONAL REQUIREMENTS:

A. <u>PCRS</u> - Project staff including HIV test counselors and Disease Investigation Specialists (DIS) or Public Health Investigators (PHI) shall interview the index clients to begin the PCRS process. Prior to the interview, the project staff shall review all available materials related to the index client's case before each interview and counseling session. Such a review shall include as many of the following information.

- information, supervisor's notes/comments, and closed field records to: (1) establish the reason for the initial examination; (2) establish possible history of STDs; (3) establish a critical period and interview period; (4) establish pregnancy status for females; (5) establish information objectives (e.g. relationship to other cases); and (6) identify any unique problems and circumstances concerning the patient (confidentiality, embarrassment, sexual orientation, cooperativeness, apathy about infections, domestic violence history, etc.).
- (2) Reviewing available socio-sexual information and attempting to verify: (1) demographics (age, DOB, race and ethnicity, sex, marital status); (2) address and phone; (3) living situation; and (4) employment and emergency locating information.
- (3) Assembling necessary materials and supplies, including: (1) visual aids; (2) writing materials (no official documents); (3) business cards; (4) disease-specific pamphlets; (5) referral

forms and envelops; (6) local map(s); and (7) phone book.

- B. Once the pre-interview analysis is complete, the DIS shall determine eligibility of index client for PCRS.

 DIS shall adhere to HIPAA regulations through out the pre-interview analysis.
- PCRS shall be offered to at least 80% of newly diagnosed HIV-positive persons whose health care provider has agreed to allow PCRS to be offered. If the index client refuses PCRS, the PCRS Liaison shall collect information from the client regarding the reasons for refusal. Information regarding index client and contact acceptance and or refusal of PCRS services shall be documented in the medical chart (when appropriate), and through the designated CDC data collection instrument. PCRS services shall continue to be offered through subsequent interactions with the patient/client through out their continuum of care. Clients returning for additional social, mental health or medical services, which have not participated in PCRS services, shall be offered PCRS. Again, acceptance and or refusal shall be documented. Bring the index client's case to the site supervisor or another DIS as needed to determine whether

the client shall be offered PCRS from another DIS. If the client accepts PCRS, they shall be counseled on their options for notifying patients.

D. The client shall always have the option to defer action at the time of the interview. If possible, DIS shall obtain locating information on all partners and suspects, regardless of the option chosen, so they are prepared to follow up on partner notification activities. Local DIS officers shall work with DIS staff from other (non LA County) jurisdictions to provide identification, counseling and testing and notification to contacts that live out of LA County. Contractor shall be able to refer index clients to the local STD Program DIS officers for follow up and or delivery of PCRS services.

E. Types of Referrals:

(1) Provider referral: Provider referral is a notification strategy where, with the consent of the infected patient, the provider takes responsibility for confidentially notifying partners of the possibility of their exposure to a STD. The DIS shall search health department open and closed records to determine whether the partner has ever been tested or treated for HIV and to seek

additional locating information. If the partner has been previously tested and/or treated, the DIS shall determine whether notification is still warranted. Notification may not be needed if the partner has been recently tested or counseled and is aware of his or her sero-positive status. If notification is needed, the DIS can use the information provided by the index client or by record search to locate and refer the partner for prevention counseling, testing, and examination. Once the partner has been located, the DIS informs him or her confidentially and privately of the possibility of his or her exposure to HIV. Information leading to the identity of the original patient is never revealed to the partner.

(2) <u>Self (Patient) Referral</u> -Self-referral (sometimes called patient referral) is the notification strategy whereby the patient with an HIV diagnosis accepts full responsibility for informing partners of their exposure to HIV and for referring them to appropriate services. When self referral is chosen, the interviewer shall coach and/or role play the following: WHEN to do the

notification-encouraging the patient to notify partners promptly; WHERE to perform the notification-encouraging a private setting; HOW to tell the partner-coaching the patient to avoid blame by stating in simple terms someone has tested positive, and because this person cares about the partner, he/she is encouraging the partner to seek examination and treatment; REACTION-asking the patient how they think the partner will react, or has reacted to difficult news in the past. Help the patient anticipate potential problems, especially in regard to loss of anonymity. If a patient has difficulty at this point, the benefits of provider referral shall be discussed and promoted.

(3) Contract Referral: Contract referral is the notification strategy in which the provider negotiates a time frame (usually 24-48 hours) for the patient to inform his or her partners of their exposure and to refer them to appropriate services. The DIS collects all locating information for all partners, suspects, or associates discussed during the interview. If the patient is unable to inform partners within an agreed-upon time period, the DIS

shall notify and refer the partners. The interviewer shall obtain identifying and locating information on partners at the time of the interview. The DIS shall also negotiate a confirmation of referral. DIS shall be prepared to discuss the pros and cons of each notification strategy, including the likelihood of verbal or physical abuse. Programs shall have in place a means of assessing the likelihood of violence as a result of partner notification and have a plan for addressing those situations.

- (4) Dual Referral: This method of Partner notification involves the client disclosing his/her HIV-positive status to a partner in the presence of the DIS in a confidential and private setting. Dual referrals can occur in a variety of settings including counseling and testing sites, a client's home, or any confidential setting that is selected by the client and agreed to by the provider.
- F. <u>Client Defers Action</u>: If the client does not feel comfortable using provider referral, the PCRS

 Provider shall work with the client to develop a plan for future disclosure. For those patients that still refuse

to go forward with the interview, the PCRS Provider shall collect the client's reason to refuse partner notification.

G. Partner Elicitation: Once the client has chosen a method of partner notification and the pre-interview analysis is completed, the PCRS Liaison shall initiate the session. If the patient is resistant to the interview process, the PCRS Liaison shall attempt to determine the reason(s) behind this unwillingness to cooperate and then address each issue, using motivational techniques such as: mode of transmission, confidentiality, asymptomatic nature of disease, consequences, social responsibility, and stigma associated with HIV. A PCRS Liaison may refer the client to another PCRS Liaison or to the STD Program. interview shall not be conducted with a third party present, even at the patient's request, unless it is for reasons of auditing PCRS Liaison performance or translation. Upon refusal of PCRS services, information shall be provided to the index client on where they can receive PCRS services if they change their mind in the future. Also, PCRS services shall be offered on a

continual basis as the patient seeks medical, mental health and/or social services.

Safety in the Field: Many field activities may pose potential unsafe situations for public health workers. Program managers shall develop and maintain detailed guidelines for ensuring DIS safety in the performance of their responsibilities. Training shall include a common sense approach to field work (appropriate dress; expensive looking jewelry, purses, and other valuables kept out of sight; car doors locked and windows rolled up; constant awareness of surroundings; and the importance of relying on instincts). DIS shall be provided picture identification (ID) and the ID shall be required to be in an employee's possession when in the field. An employee file shall be kept on each field worker that can be shared with authorities in case of emergency. This file shall include name, address, physical description, emergency locating information, a recent picture of the employee, a description of the employee's vehicle, and the vehicle license number. Other safety issues involve "occupational infections in the workplace." At a minimum, local policies and procedures shall encompass those in the

Occupational Safety and Health Administration policy

(OSHA website at www.osha.gov). Each program area shall have a local policy for avoiding occupational exposure and for dealing with such exposures, should they occur. Each DIS shall be required to practice local policies and procedures for avoiding infection(s) that could be acquired in the performance of their program responsibilities. These policies and procedures shall be regularly updated and formally reviewed with staff members at least yearly.

I. Confidentiality: Minimum professional standards for any agency handling confidential information shall include providing employees with appropriate information regarding confidential guidelines and legal regulations. All public health staff involved in partner notification activities with access to such information shall sign a confidentiality statement acknowledging the legal requirements not to disclose STD/HIV information. In addition, all activities shall adhere to HIPAA regulations. Efforts to contact and communicate with infected patients, partners, and spouses shall be carried out in a manner that preserves the confidentiality and privacy of all involved. This includes counseling

partners in a private setting; trying to notify exposed partners face-to-face; never revealing the name of the original patient to the partner; not leaving verbal messages that include HIV on answering machines; not leaving written messages that include any mention of HIV; not giving confidential information to third parties (roommates, neighbors, parents, spouses, children).

J. Field Investigations: All field investigations shall be conducted in unmarked vehicles. To avoid duplication of effort and to expand locating information, the DIS shall perform a record search immediately after initiating an investigation by reviewing available resources, including: (1) open field investigation and case interview files; (2) closed field investigation and case interview files; (3) medical records; (4) telephone white and yellow pages; (5) directory assistance; and (6) computer locator resources. The record(s) search and results shall be completely documented on the back of the field record. The DIS shall begin investigative action on priority follow-ups within one workday of assignment or of DIS initiation. When initial telephone attempts fail to reach the individual sought, or when the patient

does not follow through with a commitment, the DIS shall make a field visit within one working day or as directed by supervisor. Before leaving for the field, the DIS shall assemble standard materials and supplies, including: (1) investigative pouch; (2) maps; (3) OraQuick® Rapid HIV test kits and controls; (4) materials needed to conduct OraQuick® Rapid HIV tests; (5) venipuncture kit and/or OraSure® kits; (6) writing materials; (7) referral forms with envelopes; (8) business cards; (9) change for parking meter and public telephone (and telephone credit card, if available); (10) identification card; (11) and materials needed to perform field interviews, e.g., visual aids, consent forms. there is no response at the door of the individual sought, the DIS shall check for occupants at the side and back of the building when the way is not barred and it appears safe to do so. When the individual sought is not found, the DIS shall attempt to confirm the locating information in the initial visit by exploring all reasonable sources of information, such as: (1) other persons encountered at the address; (2) names on mailbox; (3) neighbors, apartment managers, building

superintendents; postal employees and other delivery personnel; (4) local business people; and children in the The DIS shall gather patient locating information from sources in a manner which serves to improve upon the original data provided, including previously unknown information such as: (1) full name and physical description; (2) precise address, including apartment number; (3) identity of co-residents; (4) telephone number; (5) type and place of employment; (6) hours and habits; (7) hangouts and associates; description of individual's car; (8) and where the individual can be found now. When locating information appears invalid, the DIS shall transpose house and street numbers, etc., and check similar locations in the immediate vicinity. When the individual sought is encountered in the field, the DIS shall convey a sense of urgency and motivate the patient to participate in the disease intervention process by: (1) establishing the identity of the patient; (2) engaging the patient in a private conversation; (3) identifying self and conveying the reason for visit; (4) establishing rapport and demonstrating concern; (5) informing the patient of the

STD at issue and of their risk status; (6) clustering the patient with other high-risk persons; and (7) referring the patient for the most immediate appropriate medical attention, which may include obtaining consent and collecting a specimen for testing. When the individual wants care from a non-health department provider, the DIS shall arrange or confirm the appointment personally. The DIS shall tell both the health provider and the individual of the need for recommended testing, counseling, and treatment, and determine when the test results will be available. The DIS shall obtain a signed release of information form from the patient, so that test results and treatment can be confirmed. When the individual sought is not encountered at a confirmed place of residence, the DIS may leave a referral notice in a sealed envelope marked "personal" or "confidential." Referral notices may be left by the DIS with co-residents, building managers, employers, or under the door or in any area where the referral is protected and not accessible to children or casual visitors. Referral notices are not placed in or affixed to any mail box (U.S. Postal Service Code 1702, 1705, 1708, and 1725).

The DIS shall not leave a third referral notice at the same address except with supervisor's consent. When in a safe location, the DIS shall document the results of the field investigation. The following information shall be legibly, accurately, and concisely documented on the back of the investigative form with the use of accepted abbreviations and symbols: (1) date and time of day; (2) type activity (e.g. FV=field visit); (3) persons encountered; (4) results of investigation, which may include next planned action (date and type); (5) referral specifics; and directions for difficult-to-find locations, when appropriate. When the original information fails to locate the individual, the DIS shall seek to contact the source of the information at the first reasonable opportunity in order to correct or to expand locating data. Sources to contact include: (1) the patient or others involved in a case; (2) other case managers; (3) health care providers; and (4) Interstate Transmission of STD Intervention Information desk (according to established local procedures). When there is no direct avenue to correct inadequate locating information, the DIS shall discreetly access other agency supervisor at the earliest opportunity for discussion and further action. Non-productive routine visits or dropping a referral letter is not an effective use of program resources.

L. <u>Pre-Test Counseling</u>:

DIS shall identify themselves upon approaching the contact and inform them that routine HIV counseling and testing is being made available as part of PCRS services. DIS shall explain the following: (1) the HIV testing process; (2) the use of an OraQuick® rapid HIV test; (3) only confidential testing is being offered (referrals will be provided to other clinics offering anonymous HIV testing); (4) the difference between a standard blood test, an oral (OMT) test, and the rapid test; (5) the type and method of specimen collection; (6) the waiting time for results; (7) what different results mean; (8) and confirmatory testing. brief discussion of these topics, the DIS shall confirm the individual's willingness to discuss HIV rapid testing. Upon consent (both verbal and written), the counselor shall engage the client

through the standard pre-test counseling and informed consent process.

(2)Individuals Refusing HIV Counseling and Testing: Individuals who do not wish to receive counseling and testing shall be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. Some individuals may not wish to discuss HIV counseling and testing because they are already HIV positive. In these cases, DIS shall determine if the individual is receiving medical care for his/her HIV infection, as well as providing referrals for services, including additional medical care services, and other community and psychosocial services. If a need for such services is identified, the individual shall be referred to the appropriate service provider. Referrals for medical care, social services (not limited to housing, transportation, community support, education), and mental health shall be made available to all clients regardless of their decision to test.

- (3) Individuals Accepting HIV Counseling and Testing: Demographic information shall be collected (i.e., gender, age, and race). If the potential client is found to be ineligible, the reason for ineligibility shall be recorded (e.g., underage, mental instability, etc).
- (4) Pre-test Counseling and Informed Consent: Individuals who meet the established eligibility criteria as described above, and consent to test, shall be escorted to a room or space in which counseling and testing using the OraQuick® HIV rapid test and counseling can be performed in private. The OraQuick® HIV rapid test shall be provided to clients free of charge. Only confidential tests shall be performed so that follow-up for provision of medical and psychosocial services may be accomplished. Clients who wish to test via an anonymous test shall be directed to other testing facilities where an anonymous test may be obtained. Clients agreeing to a confidential HIV rapid test shall identify a private setting in their home (or the DIS shall identify a private place in other

field settings) where the HIV counseling and testing may be performed. The room or space shall be well lit (to adequately read rapid test results) and must have a workspace with a level surface or DIS must provide a level surface (to ensure that the test kit tray is at the proper angle), and must be within acceptable temperature parameters (59° - 80°F) for performing the OraQuick® test. Staff shall explain the following: the differences and methods of standard testing (serum and/or oral fluid) and OraQuick® testing; procedures related to each of the testing options-how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat testing; and relevant information regarding the "window period" i.e., the time between possible exposure to the HIV virus and when the test is likely to identify HIV antibody in the patient specimen. If the client decides to be tested with OraQuick®, staff shall: ensure that the client understands the meaning of test results, including that a reactive OraQuick® result requires confirmatory testing; assess

client's potential reaction to receiving a reactive rapid test. Some clients may realize that they are not prepared to receive their result today and elect to have a standard test; other clients may indicate the intent to harm themselves or others based upon receiving same-day results. In these situations, testing shall be deferred and The DIS shall follow local protocols related to ensuring staff and client safety. Clients who are prepared to undergo the rapid HIV test must provide informed consent for confidential HIV testing according to local standards. The informed consent process shall also reflect the necessity of collection a blood specimen via venipuncture for individuals testing preliminary positive via OraQuick®. (HIPPA consent forms are attached).

- (5) Performing the OraQuick® Rapid HIV-1
 Antibody Test:
 - (a) Materials Required for Testing: The following materials are provided to the site:
 - (1) the OraQuick® Rapid HIV-1 Antibody Test packaged in a divided pouch that contains the

test and read the result; (2) a level, clean surface where testing can be performed; (3) temperature of the test kit and test area between 59° and 80° Fahrenheit; (4) space that assures confidentiality for both testing and counseling.

Use of External Kit Controls: Sites shall be supplied with external controls that verify whether the devices are working properly or staff is properly performing the test. The positive control (the black cap) contains a serum-based solution containing antibodies that will show a reactive result when used with the OraQuick® test. The negative control (the white cap) will show a non-reactive result when tested. If the device does not show the expected result when each control is used, either the test was not performed properly or the device is defective. Staff shall thoroughly review all of their testing procedures prior to assuming that the device is defective. External Kit Controls shall be run under the following conditions: (1) when a staff person has been trained to conduct OraQuick® testing, prior to testing client specimens; (2) when a new box of test kits is opened at the testing

site; (3) when testing conditions change; if the temperature of the test kit storage area falls outside 35°-80° Fahrenheit; (4) if the temperature of the testing area falls outside 59°-80° Fahrenheit; (5) including any of the above reasons, external controls shall be conducted at least once every twenty-five (25) tests or once a month - whichever occurs first; (6) the external controls must be refrigerated (temperature must be between 35°-46° Fahrenheit). Controls do not need to be warmed to room temperature prior to use. Although the controls have an expiration date that is one year post-production, once controls are opened they must be used within 3 weeks. Controls shall be dated when they are opened and discarded 3 weeks after this date. As a reminder, staff may wish to record on a refrigerator log when controls shall be disposed.

P. Testing Steps: Staff shall complete the following steps when administering an OraQuick® test.

More detailed instructions are delineated in the OraQuick® package insert and in the "Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test.

Staff shall familiarize themselves with both of these resources prior to testing clients.

Preparation: Cover the workspace with an (1)absorbent cover. Place stand, divided pouch, loops, antiseptic wipes, sterile retractable lancet, disposable gloves, sterile gauze, and bandages at workspace. Check expiration date of packet. If expired, dispose and obtain a new pouch that is not expired. Check to make sure there is an absorbent packet in the device side of the pouch. If none is present discard the entire pouch and obtain a new one. Open the two chambers of the divided pouch and label the test device AND the developer solution vial with a pre-printed project ID number sticker (it is also helpful to write the client code or client initials on the sticker). Keep the paddle end of the device inside the package to avoid contamination. Do Not Cover the holes on the back of the device. Remove the cap from the vial and slide it into the stand from the top. Place the cap on the absorbent cover near the stand. Put on disposable gloves.

- Standard section for detailed finger stick blood collection procedure): Clean the patient's finger with an antiseptic wipe and allow it to dry thoroughly. Using a sterile retractable lancet, puncture the skin just off the center of the finger pad. Discard lancet in a sharps container. Allow a drop of blood to form and wipe it away with sterile gauze. Allow a second drop of blood to form and place the loop onto this drop. Make sure the blood fills the inside of the loop.
- (3) Mixing: Insert the loop into the vial being careful not to touch the loop to the sides of the vial. Stir the solution with the loop to properly mix. Discard the loop in a waste container. Make sure the solution appears pink.
- (4) Testing: Remove the device from the pouch. DO NOT touch the Flat Pad. Insert the Flat Pad end of the device into the developing solution with the result window facing forward. Note the starting time on the testing log. It also may be helpful to set a timer for 20 minutes. Read the result of the

test after 20 minutes but not more than 40 minutes from the time the device was placed in the solution.

- (5) Reading the result: A valid test result must have a reddish-purple line next to the "C" (Control) triangle. If no line is present at this area, the test is invalid and no result can be interpreted. In this case, the client must be tested again. A line at only the "C" triangle, and no line at the "T" (Test) triangle, is interpreted as a non-reactive or negative test result. client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client shall be re-tested 3 months after the exposure. Lines at both the "C" and "T" area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen from the client to determine whether the client is infected with HIV.
 - (6) Assessing Invalid Results: To assess why a test may be invalid, staff shall review their procedures to determine that the test was conducted properly. A second test shall be conducted. If

materials (capped vial, device, loops, used gauze and gloves, etc.) in a trash bag. Clean any spills with a surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide). Remove gloves and wash hands after every test is performed. Use new gloves for each client.

(9) Confirmatory Testing: All clients receiving a reactive (Preliminary Positive)

OraQuick® result shall be asked for consent to immediately have a specimen collected for a confirmatory Western blot test to determine whether they have HIV infection. All clients consenting to test, shall be asked for an additional confirmatory specimen, in the event that their rapid test is preliminary positive. A serum or oral fluid specimen shall be obtained from the client and sent to a laboratory for Western blot testing (the specimen shall be sent to either the LAC Department of Health Public Health Laboratory, or a number of private laboratories throughout Los Angeles). The type of specimen collected for confirmatory testing

- (i.e., serum or oral fluid) will depend upon the type and availability of the client-requested testing methodology, and that particular project site's available testing resources.
- Q. Post-test Counseling and Referral: Post-test counseling consists of providing the results (disclosure) to the client and arranging for any follow-up testing, services, or referrals.
 - (1) Disclosure of Preliminary Positive

 (Reactive) Results: The following information shall be covered when providing post-test counseling to a client with a reactive OraQuick® result. Throughout this process, counselors shall provide emotional support to assist the client to cope while waiting for the confirmatory test. In addition, each site shall call upon their designated case manager, or social worker to assist in the provision of positive results. In the event that a client requests additional services or appointment with the client advocates, and the requested staff is not available, provisions shall be made to schedule an appointment with the client advocate for a later day. Consent

may also be obtained so that the client advocate may contact the client to schedule an appointment.

- R. Disclosure of Confirmed Positive Results:

 During the disclosure of a preliminary positive

 (reactive) results, the test counselor shall: interpret

 the result and assess client understanding of the result;

 explain confirmatory testing; obtain commitment from

 client to return for confirmatory result; discuss what

 client intends to do during waiting time, including

 disclosure issues; encourage client to take precautions

 to avoid potentially transmitting the virus to others;

 and assess need for referrals.
 - understanding of the result: Reactive results are defined as "preliminary positives" by the Centers for Disease Control and Prevention (CDC). However, this term may be confusing since all clients may not understand the word "preliminary" and "positive" has intense associations with it. By hearing the word "positive" clients may believe they are infected with HIV, regardless of how the counselor describes this screening result.

- (2) Explain confirmatory testing: A specimen for confirmatory testing shall be obtained immediately for Western blot testing. If possible, a blood specimen shall be drawn. If the counselor does not perform phlebotomy, an oral fluid specimen can be obtained. Counselors shall tell clients that if the confirmatory test result were negative, a second confirmatory test a serum test would be done to be absolutely certain that they are not infected.
- (3) Obtain commitment from client to return for confirmatory result: Counselors shall set an appointment with the client to receive the confirmatory test result. The appointment time shall be set in accordance with the amount of time necessary for confirmatory test results to be received from the local laboratory.
- (4) Discuss what client intends to do during waiting time, including disclosure issues.

 Counselors shall discuss how clients intend to cope during this waiting period and who if anyone they intend to tell about their rapid test result.

As with someone who has just received a confirmed positive result, counselors shall examine with the client who they will trust with the result, and the potential ramifications of disclosing their result widely. If their confirmatory result is negative, the client may also have to contend with contacts mistakenly believing that he/she is HIV infected.

- (5) Encourage client to take precautions to avoid potentially transmitting the virus to others:

 Counselors shall encourage and support the client in use of risk reduction behaviors to avoid potentially transmitting the virus to others. This includes examining the client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.
- (6) Assess need for referrals: The client may need emotional support during this waiting period.

 Minimally, counselors shall offer to be a support to the client via phone or in person. In addition, the client may need referrals to a mental health counselor, risk reduction specialist, or crisis line. Counselors shall assess the need for

referrals based on the steps defined in the Revised Guidelines for HIV Counseling, Testing and Referral. Counselors shall discuss the services that are available to them if their confirmatory test is positive. A brief description of partner counseling and referral services, as well as access to medical care, legal services, case management, and the drug reimbursement or health insurance programs shall be provided.

S. Disclosure of Non-reactive results: The following information shall be covered when providing post-test counseling to someone with a non-reactive OraQuick® result. Interpret the result and discuss possible need for re-testing: A non-reactive OraQuick® result is interpreted the same as for standard HIV antibody testing. The result is interpreted as negative unless the client has engaged in risk behavior within the last three months. If the client has engaged in risk behavior during this time, counselors shall recommend a re-test three months after their last exposure. In rare cases, individuals have been known to seroconvert as late as six months after an exposure. If the client has had

an exposure to someone who is known to be HIV positive, it may be advisable to recommend a re-test at six months after this exposure. Assess need for referrals:

Counselors shall assess for additional services needed by the client, such as STD or hepatitis testing, alcohol and other drug abuse treatment, economic assistance, domestic violence services, housing, etc.

T. Disclosure of Confirmed Positive Results: The following information shall be covered when providing post-test counseling to someone with a confirmed positive HIV test result. Throughout this process, counselors shall provide emotional support to assist the client to cope with their HIV+ diagnosis. In addition, each site shall call upon their designated case manager or social worker to assist in the provision of positive results. Client advocates shall offer post-disclosure services that may include emotional and community support, information/assistance regarding identification and entry into medical care, PCRS services, medical and community referrals, and follow up. In the event that a test counselor needs additional support with a client, provisions shall be made to schedule an appointment with

the client advocate for a later day. Consent may also be obtained so that the client advocate may contact the client to schedule an appointment.

- U. Result of the Confirmatory HIV Test: Sites shall follow local protocols for reporting Western Blot HIV positive results to local and CDC surveillance.
 - Result: When the DIS receives the Western Blot confirmatory HIV-positive result, they shall check the state/local HIV/AIDS reporting system to determine whether the client has been previously reported to the surveillance system. Clients that have previously tested positive for HIV are still eligible for services from the Client Advocate, but will not need to be reported to the local surveillance system. The process for providing results begins with the client's appointment for results. If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after

following this protocol, the Client Advocate shall follow the test result protocol listed below.

- (2) When the client keeps their appointment for confirmatory test results, the Client Advocate shall provide confirmatory test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. In addition, the Client Advocate shall refer the client to medical services and reassess the client for psychosocial services. Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment. If the client does not make their appointment for referrals services, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the steps outlined in the Monitoring Care services section below.
- V. Monitoring Care: After the client has been linked to medical and psychosocial services, the Client Advocate shall determine whether or not the client was successful in obtaining medical care. All project staff

shall be trained on using the OAPP HIV/AIDS Information System (HIRS) system to both obtain consent for and the enrollment of recently diagnosed clients into HIRS. staff shall take the lead in reviewing HIRS and IMACS/Casewatch data for follow up of consenting demonstration project clients. Review of their information will provide CDC with follow up information such as T-cell counts and viral load. This review process shall begin approximately three to six months after the client's appointment for confirmatory results to allow sufficient time for the client to enter care and for the lab reports to be entered into the surveillance Periodic review of the HIV/AIDS Reporting System shall occur until a T-cell and/or viral load is recorded. The Client Advocate (in this case, the Client Advocate is the case manager that is assigned to the client when they enroll in medical care services) shall ensure that all medical appointments are kept, and shall continuously offer services including PCRS. IMACS/Casewatch will provide client level reports that assess whether appointments were missed and the Client Advocate shall address missed appointments. This information shall be

included with the regular data reports that are sent to CDC.

Western Blot HIV-Negative Test Result: If the W. client does not make their appointment to obtain results of the confirmatory test, the Client Advocate (in this case, the HIV counselor/project staff) shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the HIV counselor/project staff shall follow the test result protocol listed below. When the client keeps their appointment for confirmatory test results, the Client Advocate (in this case, the HIV counselor/project staff) shall provide negative test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the Client Advocate shall instruct the patient to return for testing in one month, due to the discordant results between the OraQuick rapid HIV test and the Western Blot. When available, the confirmatory (Western Blot) test shall be done with a standard serum HIV test. If blood testing is not available, or in the absence of trained clinical staff (phlebotomist), an oral fluid test shall be used. In addition, the Client Advocate shall reassess the need

for psychosocial services. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

Western Blot Indeterminate Result: If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the test result protocol listed below. When the client keeps their appointment for confirmatory test results, the Client Advocate shall provide indeterminate test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the DIS shall recommend that the partner seek additional HIV testing in one month, due to discordant results due to the discordant results between the OraQuick rapid HIV test and the Western Blot. second Western Blot test shall be a standard serum HIV test, not an oral fluid test. In addition, the Client Advocate shall reassess the need for psychosocial services. The Client Advocates shall contact the appropriate referral service provider(s) and schedule an appointment for the client. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

Linkage to Care: LA County OAPP HIV/AIDS Information Resources System (HIRS. The HIV/AIDS Information Resources System (HIRS) is an integrated, browser-based application system designed to meet the business systems needs of LAC Office of AIDS Programs and Policy (OAPP) and its provider agencies. Upon disclosure of (confirmed) positive results, the HIV counselor/PCRS project staff registers the client into the HIRS system. The HIRS is linked to the IMACS/Caswatch system (the care services data system), which collects client demographic and diagnostic information for those clients enrolled in LA County's network of Ryan White CARE providers. HIRS is designed to ensure that the post-test return rate for persons testing HIV-positive is maximized, that all persons testing HIV-positive are effectively linked into care, and that mandated eligibility screening for people seeking CARE Act-funded services has effected the maximum use of alternate payer sources (such as MediCal, Medicaid, private insurance and VA benefits). Once the

client advocate has identified referral needs after the client has received the rapid HIV test results, the client advocate must provide a link to the referral sources for the client. If the client refuses psychosocial needs assessments, the client advocate shall provide the client with information regarding appropriate resources and contact information for each referral source. In addition, the client advocate shall schedule a confirmatory HIV test result appointment for the client. Client Advocates shall contact the appropriate referral service provider(s) and schedule an appointment for the client. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment. For HIV negative clients, resources and referrals to support groups, social and mental health services and information about community-based organizations shall be provided. For high-risk negative clients, these services may include additional risk reduction education and community and social support services, as well as testing for other STDs. The client shall also have the opportunity to schedule a post-disclosure session with the liaison, to

follow up on referrals, additional testing, or the development of a risk reduction plan. For HIV Positive clients, the PCRS Liaison is able to provide immediate access to in-house medical care, case management and social support systems during normal operating hours. For clients identified during non-operating clinic hours. In the event that a positive test occurs after operating hours, a call shall be placed to a case manager that evening with information that the client may be showing up first thing in the morning. The client shall be given a documented referral for medical care. In the event that a client tests positive at night, and the client has no one to talk with, or is not emotionally able to be left alone, a social worker shall be called in, regardless of time. After assessing the client's willingness to discuss treatment, the clients shall be referred to in-house clinicians who can begin the medical assessment and treatment enrollment for HIV-positive clients. Referrals shall be given to for other medical and treatment providers, in the event that a client wishes to receive care elsewhere. Client Advocates (PCRS liaisons, case managers, social workers medical and

mental health clinicians) shall work with the client to provide referrals that are tailored to the client's geographic, language and culture preferences. In-house client case managers or social workers shall be available to provide additional services to the client. These services include facilitation, referral and enrollment into medical care. In addition, the client advocate shall be prepared to offer other referrals for substance abuse treatment, mental health, PCRS services, and follow up.

Z. <u>Data Collection Procedures</u>: Computer systems

(Pocket PCs) - Client-level data collected for this

project shall be sent directly to the OAPP Data and

Epidemiology Unit. OAPP staff shall collect, manage,

review, analyze and disseminate this data to CDC based on

their proposed schedule of reporting. HIRS data

collection/management is described in the HIRS section of

the protocol. Client Tracking - Printed labels

containing client IDs (in sets of 8) shall be provided to

PCRS staff to facilitate the tracking of client records.

Labels shall be applied to each of the following

documents (described later) and to specimens collected

for confirmatory testing: the Initial Encounter Form/Card; the HIV Rapid Testing Demonstration Projects Questionnaire for paper versions (client ID entered into Pocket PCs for electronic version); the Test Results Log; the Client Advocate Log; OraQuick® Rapid HIV Test; and Confirmatory HIV test specimen. Initial Encounter Card: These palm-sized cards shall be utilized by PCRS staff as a record of the completed counseling and testing session. The pre-printed client ID number sticker shall be affixed to this card and passed on to the Client Advocate. will ensure that both the DIS and the Client Advocate have matching client ID number for the same client. All data shall be submitted to OAPP's Data and Epidemiology Unit for processing, management and analysis. The HIV Rapid Testing Demonstration Projects Questionnaire, to be administered using Pocket PCs, contains all data elements that shall be gathered on persons who are tested for the Specific types of data included in the questionnaire are to follow. Data collected during the initial encounter - Utilizing the Initial Encounter Card, DIS shall attempt to collect the gender, age, and race/ethnicity of all persons approached for rapid HIV

testing, regardless of willingness to participate. For persons refusing testing, DIS shall attempt to collect reasons for refusal. This data will enable investigators 1) Make comparisons between those who consented to testing with those who did not, evaluating any potential bias; and 2) Examine reasons why individuals may refuse rapid testing when offered in non-clinical settings. All initial encounter data shall be entered in Pocket PCs by the DIS. Data collected prior to rapid test - Informed consent: DIS shall, when applicable, collect reasons for a person's inability to provide informed consent. Demographic information: Site staff shall collect basic demographic information (date of birth, education status, marital status, health insurance coverage) on all persons from whom informed consent is obtained. Reasons for testing and previous testing history: DIS shall collect information on individuals' reasons for testing, their previous testing history, and any missed opportunities for testing. Information required for Test Results Log (described later): All sites conducting rapid testing with OraQuickò shall be required to maintain quality assurance logs (see Quality Assurance Logs section,

below). Prior to initiating the test, the counselor shall ensure that the client ID label has been applied to the Test Result Log, and that all other necessary information is recorded. Data collected while rapid test processes (20-40 minutes). In the event that demographic information and/or testing history data were not gathered prior to the administration of the rapid test, these data may be collected while the test is processing. HIV risk behavior: The DIS shall elicit information on client risk behavior utilizing the client-centered approach, as recommended by the Revised Guidelines for HIV Counseling, Testing and Referral. Following this discussion, the DIS shall administer specific HIV risk behavior questions from the questionnaire, recording responses into the Pocket PC. Collecting information on HIV risk in this manner ensures that project data is gathered in a standardized fashion while still adhering to current CTR guidelines. collected at post-test or beyond - HIV rapid test information: DIS or Client Advocates shall record rapid HIV test results into the handheld computer. In the event that an individual does not receive rapid HIV test

results, site staff shall also record the reason for not receiving results. Confirmatory testing data: For persons with a preliminary positive result, DIS or Client Advocates shall be required to enter confirmatory testing information into Pocket PCs (for the Questionnaire), the Test Results Log, and the Client Advocate Log (described later). To track the receipt of confirmatory test results, the Client Advocate shall gather client contact information and shall document the number and type of contact attempts to provide test results.

AA. Linkage to care: For all persons who are identified as HIV-positive, the Client Advocate shall track medical and psychosocial referrals and follow-through and shall monitor local HIV/AIDS surveillance data, recording specific values for the initial CD4 counts and viral loads of persons who are successfully linked into care. These data will serve as indicators of linkage to care for persons who are confirmed as HIV positive. Client Advocate Log: Client Advocates shall be responsible for maintaining a log that includes the Client ID, name, and contact information for persons requiring follow-up (i.e., to track confirmatory

testing results, receipt of confirmatory testing results, kept/missed appointments for medical and psychosocial referrals), as well as any notes necessary for tracking purposes. Identifying information collected for the Client Advocate log shall not be reported to CDC. log shall be kept in a locked, secure location when not being utilized by staff. Quality Assurance Logs: Each testing site shall maintain logs for quality assurance, such as those included in the appendices of the Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV Antibody Test. This information shall not be reported to CDC. Specific logs to be maintained include: Temperature Log. Site staff shall be required to record the temperature of the storage location for OraOuick test kits on a daily basis. The acceptable range for test kit storage is 20 to 27° C (35° to 80° F). For control kit storage the acceptable range is 2° to 8° C (35° to 46° F), and for the testing area is 15° to 27° C (59° to 80° F). Sites shall also be responsible for periodically (e.g., every six months) checking and documenting thermometer performance in test kit storage areas. Control Results Log: Test sites shall be required to

document information regarding controls that are run, including the test kit lot number and expiration date, the control kit lot number and expiration date, and control test results. Test Results Log. Test sites shall be required to document the following information into the test results log for each rapid HIV test that is performed: test kit lot number and expiration date; test incubation time; test result and the time at which it is reported to client; and initials of the person performing the test. For each preliminary positive test result, site staff shall also record information on confirmatory testing, including: specimen tracking number; specimen type (i.e., blood, oral fluid); and confirmatory test result and the date that it is received by the client.

AB. Monitoring and Data Collection - LA County

OAPP's Data and Epidemiology unit facilitates the

collection of data for all HCT services throughout Los

Angeles County, and shall manage the data for this

project. All participating project sites shall submit

the client level data (PDA data) to the Data and

Epidemiology Unit for management, centralization and

dissemination. The Data and Epidemiology unit shall

submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP shall conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites shall be incorporated into the existing monitoring schedule for all OAPP contracted programs.

9. Contractor shall utilize a handheld computer system for the collection and entry of data elements gathered for monitoring and evaluation purposes. Data shall be collected using the iPAQ Pocket PCs (Hewlett-Packard) via QDS software (Nova Research). In the event that the computer malfunctions, staff may need to_utilize paper and pencil assessments as an alternative for conducting evaluation activities. Contractor shall be responsible for maintenance of their computer hardware.

- A. Contractor shall provide their own computer supplies required by the data management/data reporting process. Computer supplies include: a current version of virus protection software, utilities software, software to support platform for required electronic data management, equipment maintenance contracts, insurance, diskettes and diskette mailers, toner cartridges, printer paper, and envelopes.
- B. Contractor shall be responsible for protecting the data as described in the HIV-antibody testing data collection manual, including backup and storage of current data on disk and/or tape, keyboard password protection procedures, and utilization of a current version of PC virus detection/prevention software.
- C. Contractor may seek assistance from OAPP for software installation, training, and troubleshooting, strategies for data management, and consultation on the process/management of the questionnaire from the client to the software.
- 10. <u>CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS</u>:

 Contractor shall fully comply with the Subcontracting

 Paragraph of the ADDITIONAL PROVISIONS section of this

Agreement. In addition, the Contractor shall ensure that subcontractors and consultants providing services under this Agreement shall commence services within ninety (90) days of the execution of this Agreement, or as otherwise approved by OAPP. Subcontract and consultant agreements shall be signed and dated by the Contractor's Director, or his/her designee(s), prior to commencement of subcontracted and/or consultant services.

- 11. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit:
 - A. A monthly written report together with Data Report no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP.
 - B. Data Report for HIV/AIDS counseling, testing, immune assessment, and referral services together with monthly written report no later than thirty (30) days after the end of each calendar month. Such data shall be submitted on an appropriately labeled computer diskette generated from software designated by OAPP. Such written

monthly report and computer diskette shall be mailed or delivered together to Office of AIDS Programs and Policy, 600 South Commonwealth Avenue, 6th Floor, Los Angeles, California 90005, Attention: Financial Services Division.

C. Quality Assurance for the OraQuick® Rapid HIV-1 Antibody Test, Program Monitoring and Data Collection (procedure for all clinics). LA County OAPP's Data and Epidemiology unit provides quality assurance for all OAPP contracted counseling and testing. This includes provision of technical assistance, ordering and delivery of supplies, and ordering controls. The Data and Epidemiology unit also facilitate the collection of data for all HCT services throughout Los Angeles County, and will manage the data for this project. All participating project sites will submit the client level data (PDA data) to the Data and Epidemiology Unit for management, centralization and dissemination. The Data and Epidemiology unit will submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP will conduct routine (6 month and annual) program monitoring and assessments of

agencies. During these assessments, project coordinators will be asked to report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites will be incorporated into the existing monitoring schedule for all OAPP contracted programs.

ensure that its subcontractor(s) maintain adequate health records which shall be current and kept in detail consistent with good medical and professional practice in accordance with the California Code of Regulations on each individual client. Such records shall include, but shall not be limited to: the dates of the HIV risk assessment session and the disclosure session, signed consent forms for confidential tests, test results, client interviews, progress notes documenting referrals provided, and a record of services provided by the various personnel in sufficient detail to permit an evaluation of services. The program records shall also include documentation of client demographic information and the statistical summary reports submitted monthly to OAPP. A

current list of service providers for medical, psychosocial, and other referral resources shall be maintained.

Contractor shall maintain additional program records as follows: a) letters of OAPP approval for all materials utilized by the program; b) documentation of staff job descriptions, resumes, and certificates and/or letters of completion of HIV Antibody Four-Day Counselor Certification Training, One-Day Re-certification Training, Three-Day PCRS certification and re-certification training, Two-Day Rapid HIV-1 Antibody Testing certification, as well as, selected STD and HIV training as attended; and c) documentation of an annual written evaluation of employee's performance and that completed evaluation has been discussed with employee. annual evaluation shall include, but is not limited to documentation of written bi-annual observations of the counseling session, evaluation of counselor knowledge, skills and competence to provide HIV/AIDS counseling, testing and immune assessment, and referral services.

13. PROGRAM EVALUATION: Contractor shall assess the program's quantitative and qualitative aspects. The initial program assessment shall be conducted three (3) months following approval of this Agreement; a second assessment

shall be conducted six (6) months after approval of this Agreement. The program assessments shall include:

- A. A review of the accuracy and appropriateness of the content of the counseling sessions and the educational materials provided.
- B. Observation and written evaluation of the counselors on a biannual basis. Notes on the counselor's performance and the feedback given to the counselor shall be included in his/her employee record.

Following the assessments, the Contractor shall report to OAPP on the program's progress and any problem areas following each assessment.

recommended HIV testing in Clinical Settings using the OraQuick Rapid HIV-1 Antibody test services shall be provided by individuals who are appropriately trained, qualified, who meet the guidelines set forth by the CDHS-OA and the CDC and are linguistically and culturally appropriate. All HIV risk assessment and disclosure counseling sessions shall be conducted by HIV Certified Counselors trained by the CDHS-OA and/or OAPP. All HIV Certified Counselors must attend an annual one-day HIV re-certification training approved by OAPP.

- A. In addition to certification and recertification training, Contractor shall conduct ongoing appropriate staff training. All staff is required to obtain a minimum of 16 hours of continuing education units (CEU) per each term of this agreement in addition to the required re-certification training. The required CEU training shall include, but is not limited to, Hepatitis B and C, STDs (including chlamydia, gonorrhea and syphilis), substance abuse and PCRS training.
- B. All testing unit staff providing direct services shall attend in-service training on substance abuse knowledge, substance misuser sensitivity, cultural approaches and substance misuse related issues, as directed by OAPP under the guidelines of the State Department of Alcohol and Drug Programs.
- C. Contractor shall document training activities in the monthly report to OAPP. For the purpose of this Agreement, training documentation shall include, but are not limited to: date, time and location of staff training; training topic(s), name of attendees and level of staff participation.

- D. All HIV Certified Counselors providing direct services shall be sensitive to the needs of persons of diverse life experiences including, substance users, persons with mental illness, transgenders, multiply-diagnosed individuals, etc.
- E. The Project Coordinator shall be appropriately trained and knowledgeable and demonstrate a high level of competency with respect to HIV/AIDS testing and counseling issues, STD and Hepatitis C Screening, substance misuse, community referrals, and education services. The Program Coordinator shall complete the CDHS-OA and/or OAPP's HIV Counselor Certification Training and/or comparable training as approved by OAPP.
- F. Staff vacancies shall be advertised in a local newspaper and/or posted at facilities throughout Los
 Angeles County and/or through other methods where persons with appropriate knowledge and competency can be identified. Individuals with a history of alcohol and/or drug abuse histories who are being considered for a counselor position shall have a minimum of two (2) years sobriety.

- G. Contractor shall participate in quarterly project meetings or as directed by OAPP.
- H. Contractor shall participate in all project conference calls.
- I. Contractor shall designate one person on staff as the key person for all data collection activities related to this agreement. Said staff shall be able to represent contractor on all issues related to data collection and the evaluation thereof.

Director shall notify Contractor of any revision of these guidelines, which shall become part of this Agreement.

employment or provision of service(s) and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of a tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening." Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

- approved Quality Management (QM)plan. The QM plan shall describe the process for continually assessing the contractors program effectiveness in accomplishing contractor mission, goals, and objectives. The plan shall describe the process for the following components: QM Committee, Written Policies & Procedures, Client Feedback, Program Staff, Measurable Program/Service Quality Indicators, QM Plan Implementation, and Quality Assessment & Improvement Reports.
 - A. Quality Management Committee: The QM Committee shall develop, review, and revise the agency's QM plan on an annual basis and continually assess and make recommendations for the improvement of program services. The Committee shall be responsible for developing plans of corrective action for identified program deficiencies and consist of persons that reflect the group and/or groups to whom services are targeted including clients, volunteers, program staff, management staff, consultants,

staff from other community-based organizations, etc. The Program Coordinator and a client receiving services under this contract must be included as Committee members.

Committee membership shall be described by name, title, or role, and the constituency represented (i.e., staff, management, and client). The Contractor shall review the Committee recommendations and ensure recommendations are appropriately implemented.

A separate Committee need not be created if the contracted program has an established an advisory committee or the like, so long as its composition and activities conform to the criteria described in this Agreement.

The QM Committee activities shall be documented.

Required documentation shall include but not be limited to agendas, sign-in sheets, QM Committee meeting minutes (including date, time, topics discussed, recommendations, and corrective actions).

B. Written Policies and Procedures: Policies and procedures shall be based on essential program activities and community and professional standards of care specific to this contract. The QM Plan shall describe the process

for reviewing and modifying written policies and procedures. In addition, the plan shall specify the policies be reviewed at a minimum of once a year, approved and signed by the Executive Director or designee.

- C. Client Feedback: The QM Plan shall include a mechanism for obtaining ongoing feedback from program participants regarding program effectiveness, accessibility and client satisfaction. Describe the method(s) to be used for client feedback, (e.g., satisfaction surveys, focus groups, interviews, etc). Client feedback shall be collected on an ongoing basis or at a minimum of quarterly. Describe how client feedback data will be managed by the QM committee and used to make improvements to the program.
- D. Program Staff: The QM plan shall describe the process for developing, training and monitoring staff.

 This description shall include minimum qualifications for each program staff position and a description of the methods and instruments to be used to monitor staff performance. The QM plan shall specify that staff is evaluated annually.

- Measurable Program/Service Quality Indicators: Measurable quality indicators are intended to address how well services are being provided. By developing a set of indicators specific to each program, establishing a measurable minimum standard for each indicator, and conducting an assessment on the extent to which the indicator is met, the Contractor shall assess the quality of service delivery on an ongoing basis. The QM Committee is responsible for developing a plan of corrective action to address any program quality deficiencies or to improve the effectiveness demonstrated by each indicator. Quality indicators shall be based on key activities described in the SERVICES TO BE PROVIDED Paragraph of this Exhibit. The QM Plan shall require measurement of and include at a minimum the following measurable program and/or services indicators:
 - 1 Process: Eighty-five (85%) test acceptance rate for clients approached for rapid testing; eighty-five percent (85%)post-test disclosure rate; one hundred percent (100%) HIV preliminary tests completing a confirmatory test; eighty percent (80%) of clients accepting referral counseling will be

linked to appropriate levels of care services; follow-up services will be conducted for one hundred percent (100%) of clients testing preliminary positive.

- 2 Outcome: Eighty percent (80%) of clients receiving Rapid Testing services will report satisfaction with Rapid Testing services they received; seventy-five percent (75%) of clients receiving services will successfully demonstrate or discuss at least one risk reduction skill or plan.
- 17. <u>QM PLAN IMPLEMENTATION</u>: Contractor shall implement its QM plan to ensure the quality of the services provided are assessed and improved on a continuous basis.
 - A. Quality Assessment and Improvement Reports: The QM Plan shall include the requirement for two (2) Quality Assessment and Improvement Reports. These reports shall be developed by the QM Committee and signed by the Executive Director. Contractor shall make the following reports available to the OAPP Program Manager at the time of the monitoring review or upon request:
 - 1 Mid-Year Report shall document program performance, results of plans of corrective action,

areas of concern identified by the QM Committee, and data collected from client feedback.

- 2 Year-End Report shall document actions addressing the findings of the Mid-Year reports and the overall program performance from Mid-Year to Year-End.
- 18. <u>EVALUATION</u>: Contractor shall implement an evaluation plan developed by the CDC. The pan is designed to demonstrate project accomplishments and monitor areas during the course of the project in order to improve the project's success.

Evaluation measure shall include, but not be limited to:

(1) number of individuals approached for rapid testing; (2)

number of individuals who agree to HIV testing and other types

of HIV testing; (3) number of individuals who receive rapid

HIV test and confirmatory results; (4) number of HIV infected

persons newly detected through rapid testing who enter into

medical care; and (5) number of HIV negative persons receiving

psychosocial service referrals. Contractors shall provide

counseling and testing data for 2002 and 2003 for comparison

purposes.

SCHEDULE 5

AIDS HEALTHCARE FOUNDATION

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

	Budget Period
	Date of Board Approval through December 31, 2004
Salaries	\$ 51,900
Employee Benefits	\$ 11,247
Total Salaries and Employee Benefits	\$ 63,147
Operating Expenses	\$ 31,940
Capital Expenditures	\$ 4,400
Other Costs	\$ -0-
Indirect Costs	\$ -0-
TOTAL PROGRAM BUDGET	\$ 99,487

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

SCHEDULE 6

AIDS HEALTHCARE FOUNDATION

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

	Budget Period
	January 1, 2005 through
	September 14, 2005
Salaries	\$ 86,500
Employee Benefits	\$ 18,745
Total Salaries and Employee Benefits	\$105,245
Operating Expenses	\$ 60,568
Capital Expenditures	\$ -0-
Other Costs	\$ -0-
Indirect Costs	\$ -0-
TOTAL PROGRAM BUDGET	\$165,813

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

EXHIBIT F-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

	1A.0			1.0	Con
	0 By 9/14/04,a minimum of 75% of identified partners of HIV positive clients will receive a partner notification session.			By 12/31/04, a minimum of 250 HIV positive clients will be offered Partner Counseling and Elicitation Services.	MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES
1A.2	1A.1	1.3	1.2	1.1	0
Conduct Partner Notification Sessions with identified partners of HIV positive clients. Document type of partner referral conducted and topics discussed during session. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	Develop documentation forms for Partner Notification sessions, consent forms, clients logs. Submit to OAPP for approval.	Complete Client Log. Log to include, but not be limited to the following; number of partners identified, number of partners who agree to test; testing results, number of confirmatory tests; number of confirmed HIV positive clients linked to medical care. Enter data into database. Document data. Submit findings to OAPP.	Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	Develop documentation forms for Partner Counseling and Elicitation Interviews, consent forms, clients logs. Submit to OAPP for approval.	
and ongoing	By 5/18/04	5/18/04 and ongoing	5/18/04 and ongoing	By 6/18/04	TIMELINE
1A.2	1A.1	15	:5	:	0
Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	TIMELINE METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

EXHIBIT F-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

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	3.0			2.0	
·	By 12/31/04, 100% of clients completing a Rapid Test will receive disclosure services.			By 12/31/04, a minimum of 127 partners of HIV positive clients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES
	3.1	2.3	2.2	2.1	
	Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Develop Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	
	By 5/18/04	5/18/04 and ongoing	5/18/04 and ongoing	By 5/18/04	TIMELINE OBJECT
	;; ;-	2.3	2.2	2.1	(
	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

EXHIBIT F-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

ed Rapid HIV Co nseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

					-
		following formats: Dual-Referral or Provider-Only Referral.			
IA.2 Completed materials will be kept on file and results documented in monthly reports to OAPP.	12/31/04 and ongoing	Conduct Partner Notification Sessions with identified partners of HIV positive clients. Document type of partner referral conducted and topics discussed during session. Partner notification services can be provided in one of the	1A.2		
IA.1 Letter(s) of OAPP approval and related material will be kept on file.	By 2/1/05	Review and revise, as needed, documentation forms for Partner Notification sessions, consent forms, clients logs. Submit to OAPP for approval.	1A.1	By 9/15/05, a minimum of 75% of identified partners of HIV positive clients will receive a partner notification session.	1A.0
1.3 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	Complete Client Log. Log to include, but not be limited to the following; number of partners identified, number of partners who agree to test; testing results, number of confirmatory tests; number of confirmed HIV positive clients linked to medical care. Enter data into database. Document data. Submit findings to OAPP.	13		
1.2 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	1.2		
1.1 Letter(s) of OAPP approval and related material will be kept on file.	By 2/1/05	Review and revise, as needed, documentation forms for Partner Counseling and Elicitation Interviews, consent forms, clients logs. Submit to OAPP for approval.	=	By 12/31/05, a minimum of 500 HIV positive clients will be offered Partner Counseling and Elicitation Services.	1.0
METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION	TIMELINE	IMPLEMENTATION ACTIVITIES		MEASURABLE OBJECTIVE(S)	

EXHIBIT F-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

3.0			2.0	
By 9/15/05, 100% of clients completing a Rapid Test will receive disclosure services.			By 9/15/05, a minimum of 255 partners of HIV positive clients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES
3.1	2.3	2.2	2.1	
Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Review and revise, as needed, Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	IMPLEMENTATION ACTIVITIES
By 10/15/04	9/15/04 and ongoing	9/15/04 and ongoing	By 10/15/04	TIMELINE
3.1	2.3	2.2	2.1	
Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) PREVENTION SERVICE FOR HIV INFECTED PERSONS SERVICES AGREEMENT

Amendment No. 3

	THIS AMENDMENT	is made and entered into this day
of _		, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	LOS ANGELES SHANTI FOUNDATION (hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) PREVENTION SERVICE FOR HIV INFECTED PERSONS SERVICES AGREEMENT", dated November 14, 2000, and further identified as Agreement No. H-207280, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and provide the changes set forth herein; and

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor will participate in the Los Angeles County Eligible Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of State and/or federal Centers for Disease Control and Prevention (CDC) funds, where there is a Service Provider Network (SPN) in the SPA in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must implement a "consumer advisory committee" with

regular meetings and consumer membership as a mechanism for

continuously assessing client need and adequacy of

Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must actively collaborate and recruit referrals

from service organizations and agencies beyond the Ryan White

CARE Act service delivery system, including, but not limited

to, substance abuse, mental health, primary health care and

social services organizations.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor's referrals to and from organizations must be noted

and tracked in the OAPP service utilization data system, and

followed up in client need and adequacy of Contractor's

services, and to obtain client feedback.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties hereto agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on November 14, 2000 and continue, in full force and effect through December 31, 2004. Said Agreement shall thereafter be renewed for a nine (9) month and two (2) week term effective January 1, 2005 through September 14, 2005, subject to the availability of Federal, State or County funds. If such funding is not forthcoming, this agreement shall terminate on December 31, 2004. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. In any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, A-1, D, D-1, D-2, E, E-1, F, F-1, and F-2, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>,

 Subparagraphs E and F, shall be added to Agreement as follows:
 - "E. During the period date of Board approval through December 31, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Forty-Nine Thousand, Seven Hundred Forty-Four Dollars (\$49,744). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 5, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Partner Counseling and Referral with HIV Testing Services.
 - F. During the period January 1, 2005 through
 September 14, 2005, the maximum obligation of County for
 all services provided hereunder shall not exceed EightyTwo Thousand, Nine Hundred Six Dollars (\$82,906). Such

maximum obligation is comprised entirely of CDC funds.

This sum represents the total maximum obligation of

County as shown in Schedule 6, attached hereto and

incorporated herein by reference. Such funds shall be

used entirely for the Advancing HIV Prevention

Initiative, Partner Counseling and Referral with HIV

Testing Services."

- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder for actual

 reimbursable net cost basis as set forth in Schedules 1,

 2, 3, and 4, 5, and 6, and the <u>COST REIMBURSEMENT</u>

 Paragraph of this Agreement."
- 6. Paragraph 16, <u>HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996</u> shall be added to Agreement as follows:
 - "16. HEALTH INSURANCE PORTABILITY AND

ACCOUNTABILITY ACT OF 1996: The parties acknowledge the existence of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"). Contractor understands and agrees that as a provider of medical treatment services, it is a

"covered entity" under HIPAA and, as such, has obligations with respect to the confidentiality, privacy and security of patients' medical information, and must take certain steps to preserve the confidentiality of this information, both internally and externally, including the training of its staff and the establishment of proper procedures for the release of such information, and the use of appropriate consents and authorizations specified under HIPAA.

The parties acknowledge their separate and independent obligations with respect to HIPAA, and that such obligations relate to transactions and code sets, privacy, and security. Contractor understands and agrees that it is separately and independently responsible for compliance with HIPAA in all these areas and that County has not undertaken any responsibility for compliance on Contractor's behalf. Contractor has not relied, and will not in any way rely, on County for legal advice or other representations with respect to Contractor's obligations under HIPAA, but will independently seek its own counsel and take the necessary measures to comply with the law and its implementing regulations.

Contractor and County understand and agree that each is independently responsible for HIPAA compliance and agree to take all necessary and reasonable actions to comply with the requirements of the HIPAA law and implementing regulations related to transactions and code set, privacy, and security. Each party further agrees to indemnify and hold harmless the other party (including their officers, employees, and agents), for its failure to comply with HIPAA."

- 7. Exhibits F, F-1, and F-2, SCOPES OF WORK FOR HIV/AIDS PREVENTION FOR HIV INFECTED PERSONS PARTNER COUNSELING AND REFERRAL WITH HIV TESTING SERVICES, are attached hereto and incorporated herein by reference.
- 8. Schedules 5 and 6, BUDGETS FOR HIV/AIDS PREVENTION FOR HIV INFECTED PERSONS PARTNER COUNSELING AND REFERRAL WITH HIV TESTING SERVICES, are attached hereto and incorporated herein by reference.
- 9. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COI	UNTY OF LOS ANGELES
Ву	
	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
LOS	S ANGELES SHANTI FOUNDATION
	Contractor
Ву	
-	Signature
	Printed Name
Tit	:le
	(AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

DEPARTMENT OF HEALTH SERVICES

APPROVED AS TO CONTRACT ADMINISTRATION:

By ______ Irene E. Riley, Director Contract Administration

EXHIBIT F

LOS ANGELES SHANTI FOUNDATION

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES AGREEMENT

1. <u>DEFINITION</u>: Partner counseling and referral services (PCRS) with HIV testing using the OraQuick Rapid HIV-1 antibody test services provide PCRS to HIV-positive individuals; HIV testing services to identified sex or injection drug use partners; pre-and post-test counseling for HIV antibodies; referrals to appropriate health and social services as needed by client; and the provision of appropriate HIV risk reduction intervention based on client's need. Such services shall be provided through clinics, health facilities, or non-clinic based community services providers. For the purposes of this Agreement, a linked referral is any referral that is facilitated by the providers and confirmed as met by the referring agency. At a minimum, a linked referral must include: referral information provided in writing and verification regarding client's access to services. Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services are provided free of charge and on confidential basis.

- 2. PERSONS TO BE SERVED: PCRS services shall be provided to HIV-positive individuals whose diagnosis has been reported to the state/local health department. HIV testing using the OraQuick Rapid HIV-1 antibody test services shall be provided to identified sex or injection drug use partners that meet the following criteria: (1) are at least 12 years of age, (2) are not previously known to be HIV infected, (3) are residents of Los Angeles County, (4) are without unstable psychiatric condition, (5) are not under the influence of alcohol or other illicit drug, and (6) are not identified as a prisoner or detainee in Service Planning Areas (SPAs) 1, 2, 3, 4, 5, 6, 7, or 8 of Los Angeles County.
- 3. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period of September 15, 2003, through September 14, 2005, that portion of County's maximum obligation which is allocated under this Exhibit for PCRS with HIV testing using the OraQuick Rapid HIV-1 antibody test services shall not exceed One Hundred Thirty-Two Thousand, Six Hundred Fifty Dollars (\$132,650).

4. COMPENSATION:

A. County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedules 5 and 6. Payment for services provided hereunder shall be subject to the

provisions set forth in the <u>COST REIMBURSEMENT</u> Paragraph of this Agreement.

5. <u>SERVICE DELIVERY SITE(S)</u>: Contractor's facility where services are to be provided hereunder is located at:
1616 North La Brea Avenue, Los Angeles, California 90028 and other sites as approved by OAPP's Director.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before terminating services at such location(s) and/or before commencing such services at any other location(s). OAPP reserves the right to approve and deny all requests and will make such decisions based on the appropriateness of the request.

6. SERVICES TO BE PROVIDED: During each term of this Agreement, Contractor shall provide PCRS with HIV testing using the OraQuick Rapid HIV-1 antibody test to persons meeting the eligibility criteria, in accordance with procedures formulated and adopted by Contractor's staff, the Centers for Disease Control and Prevention (CDC); consistent with California law; California Department of Health Services (CDHS) - Office of AIDS (OA) guidelines and the terms of this Agreement. The Director of OAPP shall notify Contractor of any revisions to OAPP policies and procedures, which shall become part of this Agreement. Pre-test and disclosure

counseling shall follow Los Angeles County guidelines for HIV Prevention Counseling as adopted by the Centers for Disease Control and Prevention (CDC) and CDHS-OA. All counseling sessions shall take place in a private, face-to-face session in closed room or area that ensures patient confidentiality. All PCRS shall follow the CDC guidance on HIV PCRS. Additionally, Contractor shall provide such services as described in Exhibits F, F-1 and F-2, Scopes of Work, attached hereto and incorporated herein by reference.

Minimum services to be provided shall include, but not be limited to, the following:

- A. Provide PCRS to at least 80% of newly diagnosed HIV-positive persons upon acceptance by client.

 Individuals who do not wish to receive PCRS will be asked for their age, gender, race and reasons for refusal so that characteristics of non-respondents can be evaluated.
- B. Provide Confidential testing upon acceptance by client. Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. For those clients who wish to only be tested anonymously, a referral to an anonymous HCT site will be provided.

C. Provide a client-centered counseling session that engages the client in a dialogue that encourages the disclosure of unique individual needs and concerns related to HIV risk and emphasizes personal options that limit or prevent transmission of HIV. During the session the counselor should also explain the differences and methods of standard testing (serum and/or oral fluid) and OraQuick testing, the procedures related to each of the testing options, and any relevant information regarding the "window period." Additionally, the client-centered counseling session should accomplish the following: a) improve the client's self-perception of risk; b) support behavior change previously accomplished or attempted by the client; c) negotiate a workable short-term and longterm risk reduction plan based on the client's perceived ability to change his or her behavior; d) support informed decision-making about whether to be tested; e) obtain informed consent; f) obtain consent to draw a confirmatory test specimen in the event the rapid test result is preliminary positive; g) review the nexus between HIV and STD infections; h) ensure that the client understands the meaning of test results, including a reactive OraQuick result requiring confirmatory testing;

- and i) assess the client's potential reaction to receiving a reactive rapid test. The Contractor shall fully collect client demographic information using the handheld computer system using iPAQ Pocket Personal Computers provided by OAPP. All information reported on the approved device(s) and lab slips shall be voluntarily supplied by the client.
- 7. Provide an FDA-approved Rapid HIV-1 antibody test to determine the presence of HIV antibodies. The provision of screening procedures shall be preceded by a review with the client of the following areas: a) information regarding risks and benefits of the Rapid HIV-1 antibody test; b) an explanation of the meaning of the respective test results; c) an explanation of the respective testing procedures; d) information on the importance of a confirmatory test if the test result is preliminary positive; e) a review of the HIV-antibody window period; and f) completion of OAPP-approved consent form signed by the client and maintained in the client's file in accordance with the California Code of Regulations.
 - A. The HIV Certified Counselor shall ensure to follow the steps to testing using the OraQuick Rapid HIV- 1 Antibody test as delineated in the OraQuick package

insert and in the Step-by-Step Instructions for OraQuick Rapid HIV-1 Antibody Test.

- B. Conduct a client-centered disclosure counseling session that serves to provide the client with their results and that integrates the test result in a meaningful and productive manner based on their reported risk factors and consistent with their risk reduction efforts. Test results shall not be mailed, nor disclosed over the phone, nor given to anyone except the client, nor given in the presence of other persons with the exceptions stipulated by California Health and Safety Codes 121010, 121015, 121020, 120975, 120980, and 120985.
- C. The HIV Certified Counselor reviewing the client's Counseling Information shall precede the disclosure session. The HIV Certified Counselor personalizing and framing the session to the client to establish a comfortable setting by describing disclosure session steps shall precede the disclosure event. The HIV Certified Counselor shall disclose the results, review the medical interpretation of the test result and assess the client's emotional state, counseling needs, understanding of the test results, need to be re-tested based on the window period and recent risk behaviors, and

need for a confirmatory test for preliminary positive results. The HIV Certified Counselor shall assess the client's understanding of and commitment to risk reduction guidelines as well as the strength of social support and plans for and consequences of disclosure to others.

For clients testing HIV-positive, the following additional topics shall be covered in the disclosure session; a) information regarding the confirmatory test when test results are preliminary positive; b) information regarding the risk of HIV transmission to the fetus or newborn during pregnancy, during labor and delivery, and during the postpartum period if the individual is a woman or the male partner of a women of childbearing age; c) information on the risks of reinfection; e) written documentation of information and/or assistance with partner notification and/or linkage to Los Angeles County Department of Health Services Partner Counseling Referral Services (PCRS) and field follow-up services for assisted partner notification; and e) a written assessment of the client's reaction to the positive test result to determine whether referral for

psychosocial support services, including suicide prevention, is indicated.

- The HIV Certified Counselor shall assess the need for referrals and provide specific, written referrals with adequate linkages as appropriate. At a minimum, referrals to the following services shall be considered based on client risk and test results: risk reduction, prevention for HIV-infected persons, mental health counseling, partner counseling and referral services, and tuberculosis screening and drug treatment services. For HIV-positive clients written referrals to a minimum of three (3) primary medical care providers shall be provided and any other linked referrals appropriate to the immediate health and social needs of the client. The Contractor shall document all linked referrals and referral follow-up for each person served under this Agreement. The linked referral follow-up shall include, but not be limited to, the agency the person was referred to, any appointment(s) made, no show for said appointment, and follow-up plan, if the individual failed to show for confidential testing.
- F. Contractor shall comply with the Interim

 Revision of Requirements for Content of AIDS-related

Written Materials, Pictorials, Audiovisuals,

Questionnaires, Survey Instruments, and Educational

Sessions in Centers for Disease Control Assistance

Programs, as referenced in Exhibit B.

- G. Contractor shall obtain written approval from OAPP's Director for all educational materials utilized in association with this Agreement prior to its implementation.
- H. Contractor shall submit for approval such educational materials to OAPP at least thirty (30) days prior to the projected date of implementation. For the purposes of this Agreement, educational materials may include, but not limited to, written materials (e.g., curricula, pamphlets, brochures, fliers), audiovisual materials (e.g., films, videotapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings).
- I. Failure of Contractor to abide by this requirement may result in the suspension of this Agreement at the Director's sole discretion.
- J. Contractor shall utilize funds received from County for the sole purpose of providing HIV/AIDS

counseling, testing, immune assessment, and referral services.

- K. Contractor shall not utilize funds received from County for the purpose of any and all activities associated with needle exchange, including, but not limited to, purchasing and exchanging of needles.
- L. Contractor shall ensure that all staff supported by County funds are not engaged in any and all needle exchange activities.
- M. Contractor shall be responsible for reimbursing County for all funds expended on any and all activities associated with needle exchange.
- N. Any breach of these provisions shall result in the immediate termination of agreement.

8. ADDITIONAL REQUIREMENTS:

A. <u>PCRS</u> - Project staff including HIV test counselors and Disease Investigation Specialists (DIS) or Public Health Investigators (PHI) shall interview the index clients to begin the PCRS process. Prior to the interview, the project staff shall review all available materials related to the index client's case before each interview and counseling session. Such a review shall include as many of the following information.

- information, supervisor's notes/comments, and closed field records to: (1) establish the reason for the initial examination; (2) establish possible history of STDs; (3) establish a critical period and interview period; (4) establish pregnancy status for females; (5) establish information objectives (e.g. relationship to other cases); and (6) identify any unique problems and circumstances concerning the patient (confidentiality, embarrassment, sexual orientation, cooperativeness, apathy about infections, domestic violence history, etc.).
- (2) Reviewing available socio-sexual information and attempting to verify: (1) demographics (age, DOB, race and ethnicity, sex, marital status); (2) address and phone; (3) living situation; and (4) employment and emergency locating information.
- (3) Assembling necessary materials and
 supplies, including:(1) visual aids; (2) writing
 materials (no official documents); (3) business
 cards; (4) disease-specific pamphlets; (5) referral

forms and envelops; (6) local map(s); and (7) phone book.

- B. Once the pre-interview analysis is complete, the DIS shall determine eligibility of index client for PCRS.

 DIS shall adhere to HIPAA regulations through out the pre-interview analysis.
- C. PCRS shall be offered to at least 80% of newly diagnosed HIV-positive persons whose health care provider has agreed to allow PCRS to be offered. If the index client refuses PCRS, the PCRS Liaison shall collect information from the client regarding the reasons for refusal. Information regarding index client and contact acceptance and or refusal of PCRS services shall be documented in the medical chart (when appropriate), and through the designated CDC data collection instrument. PCRS services shall continue to be offered through subsequent interactions with the patient/client through out their continuum of care. Clients returning for additional social, mental health or medical services, which have not participated in PCRS services, shall be offered PCRS. Again, acceptance and or refusal shall be documented. Bring the index client's case to the site supervisor or another DIS as needed to determine whether

the client shall be offered PCRS from another DIS. If the client accepts PCRS, they shall be counseled on their options for notifying patients.

D. The client shall always have the option to defer action at the time of the interview. If possible, DIS shall obtain locating information on all partners and suspects, regardless of the option chosen, so they are prepared to follow up on partner notification activities. Local DIS officers shall work with DIS staff from other (non LA County) jurisdictions to provide identification, counseling and testing and notification to contacts that live out of LA County. Contractor shall be able to refer index clients to the local STD Program DIS officers for follow up and or delivery of PCRS services.

E. Types of Referrals:

(1) Provider referral: Provider referral is a notification strategy where, with the consent of the infected patient, the provider takes responsibility for confidentially notifying partners of the possibility of their exposure to a STD. The DIS shall search health department open and closed records to determine whether the partner has ever been tested or treated for HIV and to seek

additional locating information. If the partner has been previously tested and/or treated, the DIS shall determine whether notification is still warranted. Notification may not be needed if the partner has been recently tested or counseled and is aware of his or her sero-positive status. If notification is needed, the DIS can use the information provided by the index client or by record search to locate and refer the partner for prevention counseling, testing, and examination. Once the partner has been located, the DIS informs him or her confidentially and privately of the possibility of his or her exposure to HIV. Information leading to the identity of the original patient is never revealed to the partner.

(2) <u>Self (Patient) Referral</u> - Self-referral (sometimes called patient referral) is the notification strategy whereby the patient with an HIV diagnosis accepts full responsibility for informing partners of their exposure to HIV and for referring them to appropriate services. When self referral is chosen, the interviewer shall coach and/or role play the following: WHEN to do the

notification-encouraging the patient to notify partners promptly; WHERE to perform the notification-encouraging a private setting; HOW to tell the partner-coaching the patient to avoid blame by stating in simple terms someone has tested positive, and because this person cares about the partner, he/she is encouraging the partner to seek examination and treatment; REACTION-asking the patient how they think the partner will react, or has reacted to difficult news in the past. Help the patient anticipate potential problems, especially in regard to loss of anonymity. If a patient has difficulty at this point, the benefits of provider referral shall be discussed and promoted.

(3) Contract Referral: Contract referral is the notification strategy in which the provider negotiates a time frame (usually 24-48 hours) for the patient to inform his or her partners of their exposure and to refer them to appropriate services. The DIS collects all locating information for all partners, suspects, or associates discussed during the interview. If the patient is unable to inform partners within an agreed-upon time period, the DIS

shall notify and refer the partners. The interviewer shall obtain identifying and locating information on partners at the time of the interview. The DIS shall also negotiate a confirmation of referral. DIS shall be prepared to discuss the pros and cons of each notification strategy, including the likelihood of verbal or physical abuse. Programs shall have in place a means of assessing the likelihood of violence as a result of partner notification and have a plan for addressing those situations.

- (4) Dual Referral: This method of Partner notification involves the client disclosing his/her HIV-positive status to a partner in the presence of the DIS in a confidential and private setting. Dual referrals can occur in a variety of settings including counseling and testing sites, a client's home, or any confidential setting that is selected by the client and agreed to by the provider.
- F. Client Defers Action: If the client does not feel comfortable using provider referral, the PCRS

 Provider shall work with the client to develop a plan for future disclosure. For those patients that still refuse

to go forward with the interview, the PCRS Provider shall collect the client's reason to refuse partner notification.

G. Partner Elicitation: Once the client has chosen a method of partner notification and the pre-interview analysis is completed, the PCRS Liaison shall initiate the session. If the patient is resistant to the interview process, the PCRS Liaison shall attempt to determine the reason(s) behind this unwillingness to cooperate and then address each issue, using motivational techniques such as: mode of transmission, confidentiality, asymptomatic nature of disease, consequences, social responsibility, and stigma associated with HIV. A PCRS Liaison may refer the client to another PCRS Liaison or to the STD Program. An interview shall not be conducted with a third party present, even at the patient's request, unless it is for reasons of auditing PCRS Liaison performance or translation. Upon refusal of PCRS services, information shall be provided to the index client on where they can receive PCRS services if they change their mind in the future. Also, PCRS services shall be offered on a

continual basis as the patient seeks medical, mental health and/or social services.

Η. Safety in the Field: Many field activities may pose potential unsafe situations for public health workers. Program managers shall develop and maintain detailed guidelines for ensuring DIS safety in the performance of their responsibilities. Training shall include a common sense approach to field work (appropriate dress; expensive looking jewelry, purses, and other valuables kept out of sight; car doors locked and windows rolled up; constant awareness of surroundings; and the importance of relying on instincts). DIS shall be provided picture identification (ID) and the ID shall be required to be in an employee's possession when in the field. An employee file shall be kept on each field worker that can be shared with authorities in case of emergency. This file shall include name, address, physical description, emergency locating information, a recent picture of the employee, a description of the employee's vehicle, and the vehicle license number. Other safety issues involve "occupational infections in the workplace." At a minimum, local policies and procedures shall encompass those in the

Occupational Safety and Health Administration policy

(OSHA website at www.osha.gov). Each program area shall have a local policy for avoiding occupational exposure and for dealing with such exposures, should they occur. Each DIS shall be required to practice local policies and procedures for avoiding infection(s) that could be acquired in the performance of their program responsibilities. These policies and procedures shall be regularly updated and formally reviewed with staff members at least yearly.

I. Confidentiality: Minimum professional standards for any agency handling confidential information shall include providing employees with appropriate information regarding confidential guidelines and legal regulations. All public health staff involved in partner notification activities with access to such information shall sign a confidentiality statement acknowledging the legal requirements not to disclose STD/HIV information. In addition, all activities shall adhere to HIPAA regulations. Efforts to contact and communicate with infected patients, partners, and spouses shall be carried out in a manner that preserves the confidentiality and privacy of all involved. This includes counseling

partners in a private setting; trying to notify exposed partners face-to-face; never revealing the name of the original patient to the partner; not leaving verbal messages that include HIV on answering machines; not leaving written messages that include any mention of HIV; not giving confidential information to third parties (roommates, neighbors, parents, spouses, children).

J. Field Investigations: All field investigations shall be conducted in unmarked vehicles. To avoid duplication of effort and to expand locating information, the DIS shall perform a record search immediately after initiating an investigation by reviewing available resources, including: (1) open field investigation and case interview files; (2) closed field investigation and case interview files; (3) medical records; (4) telephone white and yellow pages; (5) directory assistance; and (6) computer locator resources. The record(s) search and results shall be completely documented on the back of the field record. The DIS shall begin investigative action on priority follow-ups within one workday of assignment or of DIS initiation. When initial telephone attempts fail to reach the individual sought, or when the patient does not follow through with a commitment, the DIS shall

make a field visit within one working day or as directed by supervisor. Before leaving for the field, the DIS shall assemble standard materials and supplies, including: (1)investigative pouch; (2) maps; (3) OraQuick® Rapid HIV test kits and controls; (4) materials needed to conduct OraQuick® Rapid HIV tests; (5) venipuncture kit and/or OraSure® kits; (6) writing materials; (7) referral forms with envelopes; (8) business cards; (9) change for parking meter and public telephone (and telephone credit card, if available); (10) identification card; (11) and materials needed to perform field interviews, e.g., visual aids, consent forms. there is no response at the door of the individual sought, the DIS shall check for occupants at the side and back of the building when the way is not barred and it appears safe to do so. When the individual sought is not found, the DIS shall attempt to confirm the locating information in the initial visit by exploring all reasonable sources of information, such as: (1) other persons encountered at the address; (2) names on mailbox; (3) neighbors, apartment managers, building superintendents; postal employees and other delivery personnel; (4) local business people; and children in the

The DIS shall gather patient locating information from sources in a manner which serves to improve upon the original data provided, including previously unknown information such as: (1) full name and physical description; (2) precise address, including apartment number; (3) identity of co-residents; (4) telephone number; (5) type and place of employment; (6) hours and habits; (7) hangouts and associates; description of individual's car; (8) and where the individual can be found now. When locating information appears invalid, the DIS shall transpose house and street numbers, etc., and check similar locations in the immediate vicinity. When the individual sought is encountered in the field, the DIS shall convey a sense of urgency and motivate the patient to participate in the disease intervention process by: (1) establishing the identity of the patient; (2) engaging the patient in a private conversation; (3) identifying self and conveying the reason for visit; (4) establishing rapport and demonstrating concern; (5) informing the patient of the STD at issue and of their risk status; (6) clustering the patient with other high-risk persons; and (7) referring the patient for the most immediate appropriate medical attention, which may

include obtaining consent and collecting a specimen for testing. When the individual wants care from a non-health department provider, the DIS shall arrange or confirm the appointment personally. The DIS shall tell both the health provider and the individual of the need for recommended testing, counseling, and treatment, and determine when the test results will be available. DIS shall obtain a signed release of information form from the patient, so that test results and treatment can be confirmed. When the individual sought is not encountered at a confirmed place of residence, the DIS may leave a referral notice in a sealed envelope marked "personal" or "confidential." Referral notices may be left by the DIS with co-residents, building managers, employers, or under the door or in any area where the referral is protected and not accessible to children or casual visitors. Referral notices are not placed in or affixed to any mail box (U.S. Postal Service Code 1702, 1705, 1708, and 1725). The DIS shall not leave a third referral notice at the same address except with supervisor's consent. When in a safe location, the DIS shall document the results of the field investigation. The following information shall be legibly, accurately,

and concisely documented on the back of the investigative form with the use of accepted abbreviations and symbols: (1) date and time of day; (2) type activity (e.g. FV=field visit); (3) persons encountered; (4) results of investigation, which may include next planned action (date and type); (5) referral specifics; and directions for difficult-to-find locations, when appropriate. When the original information fails to locate the individual, the DIS shall seek to contact the source of the information at the first reasonable opportunity in order to correct or to expand locating data. Sources to contact include: (1) the patient or others involved in a case; (2) other case managers; (3) health care providers; and (4) Interstate Transmission of STD Intervention Information desk (according to established local procedures). When there is no direct avenue to correct inadequate locating information, the DIS shall discreetly access other agency resources, such as: (1) Department of Motor Vehicles; (2) Postal Service; (3) utilities; (4) Public Assistance; (5) local schools; (6) trade unions; (7) law enforcement (jail rosters); (8) voter registration; (9) tax appraisal office; (10) fire department (directory/department of streets); (11) other

health department programs (e.g. family planning, WIC, TB, etc.); and (12) other community resources (e.g., hospitals, CBOs, etc.). When an investigation stalls, the DIS shall notify the supervisor or appropriate case manager at the earliest reasonable opportunity (not to exceed 72 hours). Supervisor's approval is needed to close unsuccessful investigations. The DIS shall complete and submit all assigned work to his or her supervisor before taking planned leave.

K. Partner Notification: Interviews shall be conducted in person and confidentially. When a partner who has been notified of his or her exposure does not seek medical evaluation, the DIS shall follow up with that partner to ensure they understand the importance of timely and appropriate medical evaluation. Stalled investigations shall be brought to the attention of a supervisor at the earliest opportunity for discussion and further action. Non-productive routine visits or dropping a referral letter is not an effective use of program resources.

L. Pre-Test Counseling:

(1) DIS shall identify themselves upon approaching the contact and inform them that routine

HIV counseling and testing is being made available as part of PCRS services. DIS shall explain the following: (1) the HIV testing process; (2) the use of an OraQuick® rapid HIV test; (3) only confidential testing is being offered (referrals will be provided to other clinics offering anonymous HIV testing); (4) the difference between a standard blood test, an oral (OMT) test, and the rapid test; (5) the type and method of specimen collection; (6) the waiting time for results; (7) what different results mean; (8) and confirmatory testing. Upon brief discussion of these topics, the DIS shall confirm the individual's willingness to discuss HIV rapid testing. Upon consent (both verbal and written), the counselor shall engage the client through the standard pre-test counseling and informed consent process.

(2) Individuals Refusing HIV Counseling and Testing: Individuals who do not wish to receive counseling and testing shall be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. Some individuals may not wish to discuss HIV counseling and testing

because they are already HIV positive. In these cases, DIS shall determine if the individual is receiving medical care for his/her HIV infection, as well as providing referrals for services, including additional medical care services, and other community and psychosocial services. If a need for such services is identified, the individual shall be referred to the appropriate service provider.

Referrals for medical care, social services (not limited to housing, transportation, community support, education), and mental health shall be made available to all clients regardless of their decision to test.

- (3) Individuals Accepting HIV Counseling and Testing: Demographic information shall be collected (i.e., gender, age, and race). If the potential client is found to be ineligible, the reason for ineligibility shall be recorded (e.g., underage, mental instability, etc).
- (4) Pre-test Counseling and Informed Consent:
 Individuals who meet the established eligibility
 criteria as described above, and consent to test,
 shall be escorted to a room or space in which

counseling and testing using the OraQuick® HIV rapid test and counseling can be performed in private. The OraQuick® HIV rapid test shall be provided to clients free of charge. Only confidential tests shall be performed so that follow-up for provision of medical and psychosocial services may be accomplished. Clients who wish to test via an anonymous test shall be directed to other testing facilities where an anonymous test may be obtained. Clients agreeing to a confidential HIV rapid test shall identify a private setting in their home (or the DIS shall identify a private place in other field settings) where the HIV counseling and testing may be performed. The room or space shall be well lit (to adequately read rapid test results) and must have a workspace with a level surface or DIS must provide a level surface (to ensure that the test kit tray is at the proper angle), and must be within acceptable temperature parameters (59° - 80°F) for performing the OraQuick® test. Staff shall explain the following: the differences and methods of standard testing (serum and/or oral fluid) and OraQuick® testing; procedures related to each of the

testing options-how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat testing; and relevant information regarding the "window period" i.e. the time between possible exposure to the HIV virus and when the test is likely to identify HIV antibody in the patient specimen. If the client decides to be tested with OraQuick®, staff shall: ensure that the client understands the meaning of test results, including that a reactive OraQuick® result requires confirmatory testing; assess client's potential reaction to receiving a reactive rapid test. Some clients may realize that they are not prepared to receive their result today and elect to have a standard test; other clients may indicate the intent to harm themselves or others based upon receiving same-day results. In these situations, testing shall be deferred and The DIS shall follow local protocols related to ensuring staff and client safety. Clients who are prepared to undergo the rapid HIV test must provide informed consent for confidential HIV testing according to local standards. The informed consent process shall also

reflect the necessity of collection a blood specimen via venipuncture for individuals testing preliminary positive via OraQuick®. (HIPPA consent forms are attached).

- (5) Performing the OraQuick® Rapid HIV-1 Antibody Test:
 - (a) Materials Required for Testing: The following materials are provided to the site:

 (1) the OraQuick® Rapid HIV-1 Antibody Test packaged in a divided pouch that contains the device; (2) reusable test stands; (3) specimen collection loops; (4) subject information pamphlets; (5) package insert; and (6) external controls (set of positive and negative).
- M. The following materials are not provided to the site but are required. Agencies must have all of these materials prior to testing: (1) latex, vinyl or nitrile disposable gloves; (2) sterile retractable lancets; (3) timer or watch capable of timing 20-60 minutes; (4) clean, disposable, absorbent workspace cover; antiseptic wipes; (5) sterile gauze pads (2"x2"); (6) small adhesive bandages; (7) biohazard sharps container and trash bags; (8) surface disinfectant (EPA-registered, hospital grade,

intermediate activity disinfectant such as Dispatch,

Virex TB, or Cavicide); (9) alcohol-based waterless hand

cleanser; (10) laboratory grade thermometers to measure

storage temperature of test devices and controls and

temperature of testing location; and (11) required forms.

- N. <u>Conditions for Testing</u>: The following conditions must be present to use OraQuick®: (1) sufficient lighting to safely and accurately perform the test and read the result; (2) a level, clean surface where testing can be performed; (3) temperature of the test kit and test area between 59° and 80° Fahrenheit; (4) space that assures confidentiality for both testing and counseling.
- O. Use of External Kit Controls: Sites shall be supplied with external controls that verify whether the devices are working properly or staff is properly performing the test. The positive control (the black cap) contains a serum-based solution containing antibodies that will show a reactive result when used with the OraQuick® test. The negative control (the white cap) will show a non-reactive result when tested. If the device does not show the expected result when each control is used, either the test was not performed properly or the device is defective. Staff shall

thoroughly review all of their testing procedures prior to assuming that the device is defective. External Kit Controls shall be run under the following conditions: (1) when a staff person has been trained to conduct OraQuick® testing, prior to testing client specimens; (2) when a new box of test kits is opened at the testing site; (3) when testing conditions change; if the temperature of the test kit storage area falls outside 35°-80° Fahrenheit; (4) if the temperature of the testing area falls outside 59°-80° Fahrenheit; (5) including any of the above reasons, external controls shall be conducted at least once every 25 tests or once a month - whichever occurs first; (6) the external controls must be refrigerated (temperature must be between 35°-46° Fahrenheit). Controls do not need to be warmed to room temperature prior to use. Although the controls have an expiration date that is one year post-production, once controls are opened they must be used within 3 weeks. Controls shall be dated when they are opened and discarded 3 weeks after this date. As a reminder, staff may wish to record on a refrigerator log when controls shall be disposed.

P. Testing Steps: Staff shall complete the following steps when administering an OraQuick® test.

More detailed instructions are delineated in the OraQuick® package insert and in the "Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test. Staff shall familiarize themselves with both of these resources prior to testing clients.

Preparation: Cover the workspace with an absorbent cover. Place stand, divided pouch, loops, antiseptic wipes, sterile retractable lancet, disposable gloves, sterile gauze, and bandages at workspace. Check expiration date of packet. expired, dispose and obtain a new pouch that is not expired. Check to make sure there is an absorbent packet in the device side of the pouch. If none is present discard the entire pouch and obtain a new one. Open the two chambers of the divided pouch and label the test device AND the developer solution vial with a pre-printed project ID number sticker (it is also helpful to write the client code or client initials on the sticker). Keep the paddle end of the device inside the package to avoid contamination. Do Not Cover the holes on the back of the device. Remove the cap from the vial and slide it into the stand from the top. Place the cap on the absorbent cover near the stand. Put on disposable gloves.

- Standard section for detailed finger stick blood collection procedure): Clean the patient's finger with an antiseptic wipe and allow it to dry thoroughly. Using a sterile retractable lancet, puncture the skin just off the center of the finger pad. Discard lancet in a sharps container. Allow a drop of blood to form and wipe it away with sterile gauze. Allow a second drop of blood to form and place the loop onto this drop. Make sure the blood fills the inside of the loop.
- (3) Mixing: Insert the loop into the vial being careful not to touch the loop to the sides of the vial. Stir the solution with the loop to properly mix. Discard the loop in a waste container. Make sure the solution appears pink.
- (4) Testing: Remove the device from the pouch. DO NOT touch the Flat Pad. Insert the Flat Pad end of the device into the developing solution with the result window facing forward. Note the starting time on the testing log. It also may be helpful to

set a timer for 20 minutes. Read the result of the test after 20 minutes but not more than 40 minutes from the time the device was placed in the solution.

- (5)Reading the result: A valid test result must have a reddish-purple line next to the "C" (Control) triangle. If no line is present at this area, the test is invalid and no result can be interpreted. In this case, the client must be tested again. A line at only the "C" triangle, and no line at the "T" (Test) triangle, is interpreted as a non-reactive or negative test result. client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client shall be re-tested 3 months after the exposure. Lines at both the "C" and "T" area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen from the client to determine whether the client is infected with HTV.
- (6) Assessing Invalid Results: To assess why a test may be invalid, staff shall review their procedures to determine that the test was conducted properly. A second test shall be conducted. If

this test is also invalid, external kit controls shall be run. If the expected results are not obtained, staff shall contact local laboratory staff. If it appears that devices are defective, the OraSure customer service department shall be contacted at 1-800-672-7873.

- (7) Documentation of the Result: Be certain that both the vial and the device within the vial have the same ID number and client code/initials. Staff shall record the date of the test and the Client Name or anonymous code on the agency "OraQuick® Rapid HIV Result Log form . The result, date and time, temperature, and counselor ID, and test reader shall also be recorded on the log. Place a checkmark in the appropriate area indicating whether the result was non-reactive or reactive, and the type of confirmatory test preformed. Provide the client with the written result. The agency keeps a copy of this result for its records.
- (8) Clean Up: Dispose of retractable lancets in a sharps container and all other used test materials (capped vial, device, loops, used gauze and gloves, etc.) in a trash bag. Clean any spills

with a surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide). Remove gloves and wash hands after every test is performed. Use new gloves for each client.

Confirmatory Testing: All clients receiving a reactive (Preliminary Positive) OraQuick® result shall be asked for consent to immediately have a specimen collected for the confirmatory Western blot test to determine whether they have HIV infection. All clients consenting to test, shall be asked for an additional confirmatory specimen, in the event that their rapid test is preliminary positive. A serum or oral fluid specimen shall be obtained from the client and sent to a laboratory for Western blot testing (the specimen shall be sent to either the LAC Department of Health Public Health Laboratory, or a number of private laboratories throughout Los Angeles). type of specimen collected for confirmatory testing (i.e., serum or oral fluid) will depend upon the type and availability of the client-requested

testing methodology, and that particular project site's available testing resources.

- Q. Post-test Counseling and Referral: Post-test counseling consists of providing the results (disclosure) to the client and arranging for any follow-up testing, services, or referrals.
 - (1) Disclosure of Preliminary Positive (Reactive) Results: The following information shall be covered when providing post-test counseling to a client with a reactive OraQuick® result. Throughout this process, counselors shall provide emotional support to assist the client to cope while waiting for the confirmatory test. In addition, each site shall call upon their designated case manager, or social worker to assist in the provision of positive results. In the event that a client requests additional services or appointment with the client advocates, and the requested staff is not available, provisions shall be made to schedule an appointment with the client advocate for a later day. Consent may also be obtained so that the client advocate may contact the client to schedule an appointment.

- R. Disclosure of Confirmed Positive Results:During the disclosure of a preliminary positive (reactive) results, the test counselor shall: interpret the result and assess client understanding of the result; explain confirmatory testing; obtain commitment from client to return for confirmatory result; discuss what client intends to do during waiting time, including disclosure issues; encourage client to take precautions to avoid potentially transmitting the virus to others; and assess need for referrals.
 - understanding of the result: Reactive results are defined as "preliminary positives" by the Centers for Disease Control and Prevention (CDC). However, this term may be confusing since all clients may not understand the word "preliminary" and "positive" has intense associations with it. By hearing the word "positive" clients may believe they are infected with HIV, regardless of how the counselor describes this screening result.
 - (2) Explain confirmatory testing: A specimen for confirmatory testing shall be obtained immediately for Western blot testing. If possible,

a blood specimen shall be drawn. If the counselor does not perform phlebotomy, an oral fluid specimen can be obtained. Counselors shall tell clients that if the confirmatory test result were negative, a second confirmatory test - a serum test - would be done to be absolutely certain that they are not infected.

- (3) Obtain commitment from client to return for confirmatory result: Counselors shall set an appointment with the client to receive the confirmatory test result. The appointment time shall be set in accordance with the amount of time necessary for confirmatory test results to be received from the local laboratory.
- waiting time, including disclosure issues.

 Counselors shall discuss how clients intend to cope during this waiting period and who if anyone they intend to tell about their rapid test result.

 As with someone who has just received a confirmed positive result, counselors shall examine with the client who they will trust with the result, and the potential ramifications of disclosing their result

- widely. If their confirmatory result is negative, the client may also have to contend with contacts mistakenly believing that he/she is HIV infected.
- (5) Encourage client to take precautions to avoid potentially transmitting the virus to others:

 Counselors shall encourage and support the client in use of risk reduction behaviors to avoid potentially transmitting the virus to others. This includes examining the client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.
- (6) Assess need for referrals: The client may need emotional support during this waiting period.

 Minimally, counselors shall offer to be a support to the client via phone or in person. In addition, the client may need referrals to a mental health counselor, risk reduction specialist, or crisis line. Counselors shall assess the need for referrals based on the steps defined in the Revised Guidelines for HIV Counseling, Testing and Referral. Counselors shall discuss the services that are available to them if their confirmatory test is positive. A brief description of partner counseling

and referral services, as well as access to medical care, legal services, case management, and the drug reimbursement or health insurance programs shall be provided.

Disclosure of Non-reactive results: The following information shall be covered when providing post-test counseling to someone with a non-reactive OraQuick® result. Interpret the result and discuss possible need for re-testing: A non-reactive OraQuick® result is interpreted the same as for standard HIV antibody testing. The result is interpreted as negative unless the client has engaged in risk behavior within the last three months. If the client has engaged in risk behavior during this time, counselors shall recommend a re-test three months after their last exposure. cases, individuals have been known to seroconvert as late as six months after an exposure. If the client has had an exposure to someone who is known to be HIV positive, it may be advisable to recommend a re-test at six months after this exposure. Assess need for referrals: Counselors shall assess for additional services needed by the client, such as STD or hepatitis testing, alcohol and other drug abuse treatment, economic assistance, domestic violence services, housing, etc.

- Disclosure of Confirmed Positive Results: The Т. following information shall be covered when providing post-test counseling to someone with a confirmed positive HIV test result. Throughout this process, counselors shall provide emotional support to assist the client to cope with their HIV+ diagnosis. In addition, each site shall call upon their designated case manager or social worker to assist in the provision of positive results. Client advocates shall offer post-disclosure services that may include emotional and community support, information/assistance regarding identification and entry into medical care, PCRS services, medical and community referrals, and follow up. In the event that a test counselor needs additional support with a client, provisions shall be made to schedule an appointment with the client advocate for a later day. Consent may also be obtained so that the client advocate may contact the client to schedule an appointment.
- U. Result of the Confirmatory HIV Test: Sites shall follow local protocols for reporting Western Blot HIV positive results to local and CDC surveillance.

- (1)Western Blot Confirmed HIV-Positive Test Result: When the DIS receives the Western Blot confirmatory HIV-positive result, they shall check the state/local HIV/AIDS reporting system to determine whether the client has been previously reported to the surveillance system. Clients that have previously tested positive for HIV are still eligible for services from the Client Advocate, but will not need to be reported to the local surveillance system. The process for providing results begins with the client's appointment for results. If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the test result protocol listed below.
- (2) When the client keeps their appointment for confirmatory test results, the Client Advocate shall provide confirmatory test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. In addition, the Client Advocate shall refer the client to medical services and

reassess the client for psychosocial services. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment. If the client does not make their appointment for referrals services, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the steps outlined in the Monitoring Care services section below.

V. Monitoring Care: After the client has been linked to medical and psychosocial services, the Client Advocate shall determine whether or not the client was successful in obtaining medical care. All project staff shall be trained on using the OAPP HIV/AIDS Information Resources System (HIRS) system to both obtain consent for and the enrollment of recently diagnosed clients into HIRS. OAPP staff shall take the lead in reviewing HIRS and IMACS/Casewatch data for follow up of consenting demonstration project clients. Review of their information will provide CDC with follow up information such as T-cell counts and viral load. This review process shall begin approximately three to six months

after the client's appointment for confirmatory results to allow sufficient time for the client to enter care and for the lab reports to be entered into the surveillance system. Periodic review of the HIV/AIDS Reporting System shall occur until a T-cell and/or viral load is recorded. The Client Advocate (in this case, the Client Advocate is the case manager that is assigned to the client when they enroll in medical care services) shall ensure that all medical appointments are kept, and shall continuously offer services including PCRS. IMACS/Casewatch will provide client level reports that assess whether appointments were missed and the Client Advocate shall address missed appointments. This information shall be included with the regular data reports that are sent to CDC.

W. Western Blot HIV-Negative Test Result: If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate (in this case, the HIV counselor/project staff) shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the HIV counselor/project staff shall follow the test result protocol listed below. When the client keeps their appointment for confirmatory

test results, the Client Advocate (in this case, the HIV counselor/project staff) shall provide negative test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the Client Advocate shall instruct the patient to return for testing in one month, due to the discordant results between the OraQuick rapid HIV test and the Western Blot. When available, the confirmatory (Western Blot) test shall be done with a standard serum HIV test. If blood testing is not available, or in the absence of trained clinical staff (phlebotomist), an oral fluid test shall be used. In addition, the Client Advocate shall reassess the need for psychosocial services. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

X. Western Blot Indeterminate Result: If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the test result protocol listed below. When the client keeps their appointment for

confirmatory test results, the Client Advocate shall provide indeterminate test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the DIS shall recommend that the partner seek additional HIV testing in one month, due to discordant results due to the discordant results between the OraQuick rapid HIV test and the Western Blot. The second Western Blot test shall be a standard serum HIV test, not an oral fluid test. In addition, the Client Advocate shall reassess the need for psychosocial services. The Client Advocates shall contact the appropriate referral service provider(s) and schedule an appointment for the client. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

Y. Linkage to Care: LA County OAPP HIV/AIDS
Information Resources System (HIRS. The HIV/AIDS
Information Resources System (HIRS) is an integrated,
browser-based application system designed to meet the
business systems needs of LAC Office of AIDS Programs and
Policy (OAPP) and its provider agencies. Upon disclosure
of (confirmed) positive results, the HIV counselor/PCRS
project staff registers the client into the HIRS system.

The HIRS is linked to the IMACS/Caswatch system (the care services data system), which collects client demographic and diagnostic information for those clients enrolled in LA County's network of Ryan White CARE providers. is designed to ensure that the post-test return rate for persons testing HIV-positive is maximized, that all persons testing HIV-positive are effectively linked into care, and that mandated eligibility screening for people seeking CARE Act-funded services has effected the maximum use of alternate payer sources (such as MediCal, Medicaid, private insurance and VA benefits). Once the client advocate has identified referral needs after the client has received the rapid HIV test results, the client advocate must provide a link to the referral sources for the client. If the client refuses psychosocial needs assessments, the client advocate shall provide the client with information regarding appropriate resources and contact information for each referral source. In addition, the client advocate shall schedule a confirmatory HIV test result appointment for the client. Client Advocates shall contact the appropriate referral service provider(s) and schedule an appointment for the client. The Client Advocate shall then contact

the referral service provider(s) to ensure that the client followed through with the appointment. For HIV negative clients, resources and referrals to support groups, social and mental health services and information about community-based organizations shall be provided. For high-risk negative clients, these services may include additional risk reduction education and community and social support services, as well as testing for other The client shall also have the opportunity to schedule a post-disclosure session with the liaison, to follow up on referrals, additional testing, or the development of a risk reduction plan. For HIV Positive clients, the PCRS Liaison is able to provide immediate access to in-house medical care, case management and social support systems during normal operating hours. For clients identified during non-operating clinic hours. In the event that a positive test occurs after operating hours, a call shall be placed to a case manager that evening with information that the client may be showing up first thing in the morning. The client shall be given a documented referral for medical care. In the event that a client tests positive at night, and the client has no one to talk with, or is not emotionally able to be

left alone, a social worker shall be called in. regardless of time. After assessing the client's willingness to discuss treatment, the clients shall be referred to in-house clinicians who can begin the medical assessment and treatment enrollment for HIV-positive clients. Referrals shall be given to for other medical and treatment providers, in the event that a client wishes to receive care elsewhere. Client Advocates (PCRS liaisons, case managers, social workers medical and mental health clinicians) shall work with the client to provide referrals that are tailored to the client's geographic, language and culture preferences. In-house client case managers or social workers shall be available to provide additional services to the client. services include facilitation, referral and enrollment into medical care. In addition, the client advocate shall be prepared to offer other referrals for substance abuse treatment, mental health, PCRS services, and follow up.

Z. Data Collection Procedures: Computer systems (Pocket PCs) - Client-level data collected for this project shall be sent directly to the OAPP Data and Epidemiology Unit. OAPP staff shall collect, manage,

review, analyze and disseminate this data to CDC based on their proposed schedule of reporting. HIRS data collection/management is described in the HIRS section of the protocol. Client Tracking - Printed labels containing client IDs (in sets of 8) shall be provided to PCRS staff to facilitate the tracking of client records. shall be applied to each of the following documents (described later) and to specimens collected for confirmatory testing: the Initial Encounter Form/Card; the HIV Rapid Testing Demonstration Projects Questionnaire for paper versions (client ID entered into Pocket PCs for electronic version); the Test Results Log; the Client Advocate Log; OraQuick® Rapid HIV Test; and Confirmatory HIV test specimen. Initial Encounter Card: These palm-sized cards shall be utilized by PCRS staff as a record of the completed counseling and testing session. The pre-printed client ID number sticker shall be affixed to this card and passed on to the Client Advocate. will ensure that both the DIS and the Client Advocate have matching client ID number for the same client. All data shall be submitted to OAPP's Data and Epidemiology Unit for processing, management and analysis. Rapid Testing Demonstration Projects Questionnaire, to be

administered using Pocket PCs, contains all data elements that shall be gathered on persons who are tested for the project. Specific types of data included in the questionnaire are to follow. Data collected during the initial encounter - Utilizing the Initial Encounter Card, DIS shall attempt to collect the gender, age, and race/ethnicity of all persons approached for rapid HIV testing, regardless of willingness to participate. persons refusing testing, DIS shall attempt to collect reasons for refusal. This data will enable investigators 1) Make comparisons between those who consented to testing with those who did not, evaluating any potential bias; and 2) Examine reasons why individuals may refuse rapid testing when offered in non-clinical settings. All initial encounter data shall be entered in Pocket PCs by the DIS. Data collected prior to rapid test - Informed consent: DIS shall, when applicable, collect reasons for a person's inability to provide informed consent. Demographic information: Site staff shall collect basic demographic information (date of birth, education status, marital status, health insurance coverage) on all persons from whom informed consent is obtained. Reasons for testing and previous testing history: DIS shall collect

information on individuals' reasons for testing, their previous testing history, and any missed opportunities for testing. Information required for Test Results Log (described later): All sites conducting rapid testing with OraQuickò shall be required to maintain quality assurance logs (see Quality Assurance Logs section, below). Prior to initiating the test, the counselor shall ensure that the client ID label has been applied to the Test Result Log, and that all other necessary information is recorded. Data collected while rapid test processes (20-40 minutes). In the event that demographic information and/or testing history data were not gathered prior to the administration of the rapid test, these data may be collected while the test is processing. HIV risk behavior: The DIS shall elicit information on client risk behavior utilizing the client-centered approach, as recommended by the Revised Guidelines for HIV Counseling, Testing and Referral. Following this discussion, the DIS shall administer specific HIV risk behavior questions from the questionnaire, recording responses into the Pocket PC. Collecting information on HIV risk in this manner ensures that project data is gathered in a standardized fashion while still adhering to current CTR

guidelines. Data collected at post-test or beyond - HIV rapid test information: DIS or Client Advocates shall record rapid HIV test results into the handheld computer. In the event that an individual does not receive rapid HIV test results, site staff shall also record the reason for not receiving results. Confirmatory testing data: For persons with a preliminary positive result, DIS or Client Advocates shall be required to enter confirmatory testing information into Pocket PCs (for the Questionnaire), the Test Results Log, and the Client Advocate Log (described later). To track the receipt of confirmatory test results, the Client Advocate shall gather client contact information and shall document the number and type of contact attempts to provide test results.

AA. Linkage to care: For all persons who are identified as HIV-positive, the Client Advocate shall track medical and psychosocial referrals and follow-through and shall monitor local HIV/AIDS surveillance data, recording specific values for the initial CD4 counts and viral loads of persons who are successfully linked into care. These data will serve as indicators of linkage to care for persons who are

confirmed as HIV positive. Client Advocate Log: Client Advocates shall be responsible for maintaining a log that includes the Client ID, name, and contact information for persons requiring follow-up (i.e., to track confirmatory testing results, receipt of confirmatory testing results, kept/missed appointments for medical and psychosocial referrals), as well as any notes necessary for tracking purposes. Identifying information collected for the Client Advocate log shall not be reported to CDC. log shall be kept in a locked, secure location when not being utilized by staff. Quality Assurance Logs: Each testing site shall maintain logs for quality assurance. such as those included in the appendices of the Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV Antibody Test. This information shall not be reported to CDC. Specific logs to be maintained include: Temperature Log. Site staff shall be required to record the temperature of the storage location for OraQuick test kits on a daily basis. The acceptable range for test kit storage is 2° to 27° C (35° to 80° F). For control kit storage the acceptable range is 2° to 8° C (35° to 46° F), and for the testing area is 15° to 27° C (59° to 80° F). Sites shall also be responsible for periodically

(e.g., every six months) checking and documenting thermometer performance in test kit storage areas. Control Results Log: Test sites shall be required to document information regarding controls that are run, including the test kit lot number and expiration date, the control kit lot number and expiration date, and control test results. Test Results Log. Test sites shall be required to document the following information into the test results log for each rapid HIV test that is performed: test kit lot number and expiration date; test incubation time; test result and the time at which it is reported to client; and initials of the person performing the test. For each preliminary positive test result, site staff shall also record information on confirmatory testing, including: specimen tracking number; specimen type (i.e., blood, oral fluid); and confirmatory test result and the date that it is received by the client.

AB. Monitoring and Data Collection - LA County
OAPP's Data and Epidemiology unit facilitates the
collection of data for all HCT services throughout Los
Angeles County, and shall manage the data for this
project. All participating project sites shall submit
the client level data (PDA data) to the Data and

Epidemiology Unit for management, centralization and dissemination. The Data and Epidemiology unit shall submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP shall conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites shall be incorporated into the existing monitoring schedule for all OAPP contracted programs.

9. Contractor shall utilize a handheld computer system for the collection and entry of data elements gathered for monitoring and evaluation purposes. Data shall be collected using the iPAQ Pocket PCs (Hewlett-Packard) via QDS software (Nova Research). In the event that the computer malfunctions, staff may need to_utilize paper and pencil assessments as an alternative for conducting evaluation activities. Contractor shall be responsible for maintenance of their computer hardware.

- A. Contractor shall provide their own computer supplies required by the data management/data reporting process. Computer supplies include: a current version of virus protection software, utilities software, software to support platform for required electronic data management, equipment maintenance contracts, insurance, diskettes and diskette mailers, toner cartridges, printer paper, and envelopes.
- B. Contractor shall be responsible for protecting the data as described in the HIV-antibody testing data collection manual, including backup and storage of current data on disk and/or tape, keyboard password protection procedures, and utilization of a current version of PC virus detection/prevention software.
- C. Contractor may seek assistance from OAPP for software installation, training, and troubleshooting, strategies for data management, and consultation on the process/management of the questionnaire from the client to the software.
- 10. <u>CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS</u>:

 Contractor shall fully comply with the Subcontracting

 Paragraph of the ADDITIONAL PROVISIONS section of this

 Agreement. In addition, the Contractor shall ensure that

subcontractors and consultants providing services under this Agreement shall commence services within ninety (90) days of the execution of this Agreement, or as otherwise approved by OAPP. Subcontract and consultant agreements shall be signed and dated by the Contractor's Director, or his/her designee(s), prior to commencement of subcontracted and/or consultant services.

- 11. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit:
 - A. A monthly written report together with Data Report no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP.
 - B. Data Report for HIV/AIDS counseling, testing, immune assessment, and referral services together with monthly written report no later than thirty (30) days after the end of each calendar month. Such data shall be submitted on an appropriately labeled computer diskette generated from software designated by OAPP. Such written monthly report and computer diskette shall be mailed or delivered together to Office of AIDS Programs and Policy,

600 South Commonwealth Avenue, 6th Floor, Los Angeles, California 90005, Attention: Financial Services
Division.

C. Quality Assurance for the OraQuick® Rapid HIV-1 Antibody Test, Program Monitoring and Data Collection (procedure for all clinics). LA County OAPP's Data and Epidemiology unit provides quality assurance for all OAPP contracted counseling and testing. This includes provision of technical assistance, ordering and delivery of supplies, and ordering controls. The Data and Epidemiology unit also facilitate the collection of data for all HCT services throughout Los Angeles County, and will manage the data for this project. All participating project sites will submit the client level data (PDA data) to the Data and Epidemiology Unit for management, centralization and dissemination. The Data and Epidemiology unit will submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP will conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will be asked to report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites will be incorporated into the existing monitoring schedule for all OAPP contracted programs.

PROGRAM RECORDS: Contractor shall maintain and/or ensure that its subcontractor(s) maintain adequate health records which shall be current and kept in detail consistent with good medical and professional practice in accordance with the California Code of Regulations on each individual client. Such records shall include, but shall not be limited to: the dates of the HIV risk assessment session and the disclosure session, signed consent forms for confidential tests, test results, client interviews, progress notes documenting referrals provided, and a record of services provided by the various personnel in sufficient detail to permit an evaluation of services. The program records shall also include documentation of client demographic information and the statistical summary reports submitted monthly to OAPP. A current list of service providers for medical, psychosocial, and other referral resources shall be maintained.

Contractor shall maintain additional program records as follows: a) letters of OAPP approval for all materials

utilized by the program; b) documentation of staff job descriptions, resumes, and certificates and/or letters of completion of HIV Antibody Four-Day Counselor Certification Training, One-Day Re-certification Training, Three-Day PCRS certification and re-certification training, Two-Day Rapid HIV-1 Antibody Testing certification, as well as, selected STD and HIV training as attended; and c) documentation of an annual written evaluation of employee's performance and that completed evaluation has been discussed with employee. This annual evaluation shall include, but is not limited to documentation of written bi-annual observations of the counseling session, evaluation of counselor knowledge, skills and competence to provide HIV/AIDS counseling, testing and immune assessment, and referral services.

- 13. PROGRAM EVALUATION: Contractor shall assess the program's quantitative and qualitative aspects. The initial program assessment shall be conducted three (3) months following approval of this Agreement; a second assessment shall be conducted six (6) months after approval of this Agreement. The program assessments shall include:
 - A. A review of the accuracy and appropriateness of the content of the counseling sessions and the educational materials provided.

- B. Observation and written evaluation of the counselors on a biannual basis. Notes on the counselor's performance and the feedback given to the counselor shall be included in his/her employee record. Following the assessments, the Contractor shall report to OAPP on the program's progress and any problem areas following each assessment.
- 13. ADDITIONAL STAFFING REQUIREMENTS: The Routinely recommended HIV testing in Clinical Settings using the OraQuick Rapid HIV-1 Antibody test services shall be provided by individuals who are appropriately trained, qualified, who meet the guidelines set forth by the CDHS-OA and the CDC and are linguistically and culturally appropriate. All HIV risk assessment and disclosure counseling sessions shall be conducted by HIV Certified Counselors trained by the CDHS-OA and/or OAPP. All HIV Certified Counselors must attend an annual one-day HIV re-certification training approved by OAPP.
 - A. In addition to certification and re-certification training, Contractor shall conduct ongoing appropriate staff training. All staff is required to obtain a minimum of 16 hours of continuing education units (CEU) per each term of this agreement in addition to the required recertification training. The required CEU training shall

include, but is not limited to, Hepatitis B and C, STDs (including chlamydia, gonorrhea and syphilis), substance abuse and PCRS training.

- B. All testing unit staff providing direct services shall attend in-service training on substance abuse knowledge, substance misuser sensitivity, cultural approaches and substance misuse related issues, as directed by OAPP under the guidelines of the State Department of Alcohol and Drug Programs.
- C. Contractor shall document training activities in the monthly report to OAPP. For the purpose of this Agreement, training documentation shall include, but are not limited to: date, time and location of staff training; training topic(s), name of attendees and level of staff participation.
- D. All HIV Certified Counselors providing direct services shall be sensitive to the needs of persons of diverse life experiences including, substance users, persons with mental illness, transgenders, multiply-diagnosed individuals, etc.
- E. The Project Coordinator shall be appropriately trained and knowledgeable and demonstrate a high level of competency with respect to HIV/AIDS testing and counseling

issues, STD and Hepatitis C Screening, substance misuse, community referrals, and education services. The Program Coordinator shall complete the CDHS-OA and/or OAPP's HIV Counselor Certification Training and/or comparable training as approved by OAPP.

- F. Staff vacancies shall be advertised in a local newspaper and/or posted at facilities throughout Los Angeles County and/or through other methods where persons with appropriate knowledge and competency can be identified. Individuals with a history of alcohol and/or drug abuse histories who are being considered for a counselor position shall have a minimum of two (2) years sobriety.
- G. Contractor shall participate in quarterly project meetings or as directed by OAPP.
- H. Contractor shall participate in all project conference calls.
- I. Contractor shall designate one person on staff as the key person for all data collection activities related to this agreement. Said staff shall be able to represent contractor on all issues related to data collection and the evaluation thereof.

Director shall notify Contractor of any revision of these guidelines, which shall become part of this Agreement.

14. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of service(s) and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of a tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening." Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

approved Quality Management (QM)plan. The QM plan shall describe the process for continually assessing the contractors program effectiveness in accomplishing contractor mission, goals, and objectives. The plan shall describe the process for the following components: QM Committee, Written Policies & Procedures, Client Feedback, Program Staff, Measurable

Program/Service Quality Indicators, QM Plan Implementation, and Quality Assessment & Improvement Reports.

Quality Management Committee: The OM Committee shall develop, review, and revise the agency's QM plan on an annual basis and continually assess and make recommendations for the improvement of program services. The Committee shall be responsible for developing plans of corrective action for identified program deficiencies and consist of persons that reflect the group and/or groups to whom services are targeted including clients, volunteers, program staff, management staff, consultants, staff from other community-based organizations, etc. Program Coordinator and a client receiving services under this contract must be included as Committee members. Committee membership shall be described by name, title, or role, and the constituency represented (i.e., staff, management, and client). The Contractor shall review the Committee recommendations and ensure recommendations are appropriately implemented.

A separate Committee need not be created if the contracted program has an established an advisory committee or the like, so long as its composition and activities conform to the criteria described in this

Agreement. The QM Committee activities shall be documented. Required documentation shall include but not be limited to agendas, sign-in sheets, QM Committee meeting minutes (including date, time, topics discussed, recommendations, and corrective actions).

- B. Written Policies and Procedures: Policies and procedures shall be based on essential program activities and community and professional standards of care specific to this contract. The QM Plan shall describe the process for reviewing and modifying written policies and procedures. In addition, the plan shall specify the policies be reviewed at a minimum of once a year, approved and signed by the Executive Director or designee.
- C. Client Feedback: The QM Plan shall include a mechanism for obtaining ongoing feedback from program participants regarding program effectiveness, accessibility and client satisfaction. The QM plan shall describe the method(s) to be used for client feedback, (e.g., satisfaction surveys, focus groups, interviews, etc). Client feedback shall be collected on an ongoing basis or at a minimum of quarterly. The QM plan shall describe how client feedback data will be managed by the

QM committee and used to make improvements to the program.

- D. Program Staff: The QM plan shall describe the process for developing, training and monitoring staff.

 This description shall include minimum qualifications for each program staff position and a description of the methods and instruments to be used to monitor staff performance. The QM plan shall specify that staff is evaluated annually.
- E. Measurable Program/Service Quality Indicators:

 Measurable quality indicators are intended to address how well services are being provided. By developing a set of indicators specific to each program, establishing a measurable minimum standard for each indicator, and conducting an assessment on the extent to which the indicator is met, the Contractor shall assess the quality of service delivery on an ongoing basis. The QM

 Committee is responsible for developing a plan of corrective action to address any program quality deficiencies or to improve the effectiveness demonstrated by each indicator. Quality indicators shall be based on key activities described in the SERVICES TO

 BE PROVIDED Paragraph of this Exhibit. The QM Plan shall

require measurement of and include at a minimum the following measurable program and/or services indicators:

- (1) Process: Eighty-five (85%) test acceptance rate for clients approached for rapid testing; eighty-five percent (85%)post-test disclosure rate; one hundred percent (100%) HIV preliminary tests completing a confirmatory test; eighty percent (80%) of clients accepting referral counseling will be linked to appropriate levels of care services; follow-up services will be conducted for one hundred percent (100%) of clients testing preliminary positive.
- (2) Outcome; Eighty percent (80%) of clients receiving Rapid Testing services will report satisfaction with Rapid Testing services they received; seventy-five percent (75%) of clients receiving services will successfully demonstrate or discuss at least one risk reduction skill or plan.
- 16. <u>OM PLAN IMPLEMENTATION</u>: Contractor shall implement its QM plan to ensure the quality of the services provided are assessed and improved on a continuous basis.
 - A. Quality Assessment and Improvement Reports: The QM Plan shall include the requirement for two (2) Quality

Assessment and Improvement Reports. These reports shall be developed by the QM Committee and signed by the Executive Director. Contractor shall make the following reports available to the OAPP Program Manager at the time of the monitoring review or upon request:

- (1) Mid-Year Report shall document program performance, results of plans of corrective action, areas of concern identified by the QM Committee, and data collected from client feedback.
- (2) Year-End Report shall document actions addressing the findings of the Mid-Year reports and the overall program performance from Mid-Year to Year-End.
- evaluation plan developed by the CDC. The pan is designed to demonstrate project accomplishments and monitor areas during the course of the project in order to improve the project's success. Evaluation measure shall include, but not be limited to: (1) number of individuals approached for rapid testing; (2) number of individuals who agree to HIV testing and other types of HIV testing; (3) number of individuals who receive rapid HIV test and confirmatory results; (4) number of HIV infected persons newly detected through rapid testing who

enter into medical care; and (5) number of HIV negative persons receiving psychosocial service referrals. Contractors shall provide counseling and testing data for 2002 and 2003 for comparison purposes.

SCHEDULE 5

LOS ANGELES SHANTI FOUNDATION

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

	Budget Period
	Date of Board Approval through December 31, 2004
Salaries	\$ 34,425
Employee Benefits	\$ 6,740
Total Salaries and Benefits	\$ 41,165
Operating Expenses	\$ 8,579
Capital Expenditures	\$ -0-
Other Costs	\$ -0-
Indirect Costs	\$ -0-
TOTAL PROGRAM BUDGET	\$ 49,744

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

EXHIBIT F-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

1.0	MEASURABLE OBJECTIVE(S) 1.0 By 12/31/04, a minimum of 125 HIV positive clients will be offered Partner Counseling and Elicitation Services. 1.2	1.1	IMPLEMENTATION ACTIVITIES Develop documentation forms for Partner Counseling and Elicitation Interviews, consent forms, clients logs. Submit to OAPP for approval. Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	TIMELINE By 5/18/04 1.1 5/18/04 and ongoing 1.2	-	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION Letter(s) of OAPP approval and related material will be kept on file. Completed materials will be kept on file and results documented in monthly reports to OAPP.
		1.3	Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral. Complete Client Log. Lob to include, but not be limited to the following; number of partners identified, number of partners who agree to test; testing results, number of confirmed HIV positive clients linked to medical care. Enter data into database. Document data. Submit findings to OAPP.	and ongoing 5/18/04 and ongoing	र्क <u>र</u> स	
1A.0	By 12/31/04,a minimum of 75% of identified partners of HIV positive clients will receive a partner notification session.	1A.1	Develop documentation forms for Partner Notification sessions, consent forms, clients logs. Submit to OAPP for approval.	By 5/18/04	04	04 1A.1
		1A.2	Conduct Partner Notification Sessions with identified partners of HIV positive clients. Document type of partner referral conducted and topics discussed during session. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	3/18/04 and ongoing	going	going 1A.2

EXHIBIT F-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

			Т	
3.0)		2.0	
By 12/31/04, 100% of cilents completing a Kapid Test will receive disclosure services.			By 12/31/04, a minimum of 64 partners of HIV positive clients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES
	2.3	2.2	2.1	
topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Develop Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	IMPLEMENTATION ACTIVITIES
Бу Элголин	5/18/04 and ongoing	5/18/04 and ongoing	By 5/18/04	ANITAMIL
3.1	2.3	2.2	2.1	c
results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

EXHIBIT F-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

nseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angdes County.

——————————————————————————————————————					
	1.0			1A.0	
MEASURABLE OBJECTIVE(S)	By 12/31/05, a minimum of 250 HIV positive clients will be offered Partner Counseling and Elicitation Services.			By 12/31/05,a minimum of 75% of identified partners of HIV positive clients will receive a partner notification session.	
	1.1	1.2	1.3	1A.1	1A.2
MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES TIMELINE OBJECTIVE(S) AND DOCUMENTATION	Review and revise, as needed, documentation forms for Partner Counseling and Elicitation Interviews, consent forms, clients logs. Submit to OAPP for approval.	Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	Complete Client Log. Lob to include, but not be limited to the following; number of partners identified, number of partners who agree to test; testing results, number of confirmatory tests; number of confirmed HIV positive clients linked to medical care. Enter data into database. Document data. Submit findings to OAPP.	Review and revise, as needed, documentation forms for Partner Notification sessions, consent forms, clients logs. Submit to OAPP for approval.	Conduct Partner Notification Sessions with identified partners of HIV positive clients. Document type of partner referral conducted and topics discussed during session. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.
ANITAMIL	Ву 2/1/05	1/1/05 and ongoing	1/1/05 and ongoing	By 2/1/05	1/1/05 and ongoing
01	<u>-</u>	1.2	1.3	1A.1	1A.2
METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION	Letter(s) of OAPP approval and related material will be kept on file.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	Completed materials will be kept on file and results documented in monthly reports to OAPP.

EXHIBIT F-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

	3.0			2	
	.			2.0	
	By 12/31/05, 100% of clients completing a Rapid Test will receive disclosure services.			By 12/31/05, a minimum of 128 partners of HIV positive clients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S)
	3.1 1	2.3	2.2	2.1	
	Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on IPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Review and revise, as needed, Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling: Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES TIMELINE OBJECTIVE(S) AND DOCUMENTATION
	By 2/1/05	1/1/05 and ongoing	1/1/05 and ongoing	By 2/1/05	TIMELINE
	3.1	23	2.2	2.1	
·	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AMBULATORY OUTPATIENT MEDICAL SERVICES AGREEMENT

Amendment No. 12

	THIS AMENDMENT	is made and entered into this day
of _	4 7	, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	ALTAMED HEALTH SERVICES CORP. (hereafter "Contractor")

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME AMBULATORY OUTPATIENT MEDICAL SERVICES", dated April 1, 1997, and further identified as Agreement No. H-2090203, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and provide the changes set forth herein; and

WHEREAS, funds received under the CARE Act will be utilized to supplement, not supplant, State, federal, or local funds made available in the year for which funding is awarded to provide HIV-related services to individuals with HIV disease.

WHEREAS, as a recipient of CARE Act funds, Contractor will participate in the Los Angeles County Eligible
Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of CARE Act funds, where there is a Service Provider Network (SPN) in the Service Planning Area (SPA) in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of CARE Act funds, Contractor must implement a "consumer advisory committee" with regular meetings and consumer membership as a mechanism for continuously assessing client need and adequacy of Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of CARE Act funds, Contractor must actively collaborate and recruit referrals from service organizations and agencies beyond the Ryan White CARE Act service delivery system, including, but not limited to, substance abuse, mental health, primary health care and social services organizations.

WHEREAS, as a recipient of CARE Act funds, Contractor's referrals to and from organizations must be noted and tracked in the Office of AIDS Programs and Policy (OAPP) service utilization data system, and followed up in cases where client

does not make or present for appointment in accordance with Contractor's referral guidelines.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on April 4, 1997 and continue in full force and effect through February 28, 2005. Said Agreement shall thereafter be automatically renewed for two (2) twelve (12) month periods, effective March 1, 2005 through February 28, 2006, and March 1, 2006 through February 28, 2007 and one (1) six (6) month period, effective March 1, 2007 through August 31, 2007, subject to the availability of federal, State, or County funding sources. If such funding sources are not forthcoming, this Agreement shall terminate February 28, 2005. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance

written notice thereof to County. In any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, H, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z, AA, BB, and CC attached hereto and incorporated herein by reference."
- 4. Paragraph 3, MAXIMUM OBLIGATION OF COUNTY,

 Subparagraph H, I, J, and K, shall be added to agreement as

 follows:
 - "H. During the period date of Board approval through February 28, 2005, the maximum obligation of County for all services provided hereunder shall not exceed Thirty-Two Thousand, Eighty-Three Dollars (\$32,083). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 67, attached hereto and incorporated herein by reference. Such funds shall be

used entirely for the Special Projects of National Significance, Prevention with Positives Services.

- I. During the period date of March 1, 2005 through February 28, 2006, the maximum obligation of County for all services provided hereunder shall not exceed Thirty-Five Thousand Dollars (\$35,000). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 68, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.
- J. During the period March 1, 2006 through February 28, 2007, the maximum obligation of County for all services provided hereunder shall not exceed Thirty-Five Thousand Dollars (\$35,000). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 69, attached hereto and incorporated herein by reference.

Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.

- K. During the period March 1, 2007 through August 31, 2007, the maximum obligation of County for all services provided hereunder shall not exceed Twenty Thousand, Four Hundred Seventeen Dollars (\$20,417). Such maximum obligation is comprised entirely of Centers for Disease Control and Prevention (CDC) funds. This sum represents the total maximum obligation of County as shown in Schedule 70, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services."
- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder for actual

 reimbursable net costs as set forth in Schedules 1, 2, 3
 B, 4-A, 5,6,7,10, 13, 14, 16, 17, 20, 21, 22, 23, 24, 25,

 28, 33, 34, 37, 40, 45, 50, 53, 55, 56, 57, 61, 62, 66,

 67, 68, 69, and 70, and on a fee-for-service basis as set

 forth in Schedules 26, 27, 29, 30, 31, 32, 35, 36, 38,

- 39, 42, 43, 44, 46, 47, 48, 51, 52, 54, 58, 59, 60, 63, 64, and 65, and the FEE-FOR-SERVICE REIMBURSEMENT

 Paragraph of this Agreement."
- 6. Exhibit CC, SCOPE OF WORK FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE, PREVENTION WITH POSITIVES SERVICES, is attached to this Amendment and incorporated in Agreement by reference.
- 7. Schedules 67, 68, 69, and 70, BUDGETS FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE, PREVENTION WITH POSITIVES SERVICES, are attached to this Amendment and incorporated in Agreement by reference.
- 8. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

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Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COU	UNTY OF LOS ANGELES
Ву	
-	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
ALI	AMED HEALTH SERVICES CORPORATION
	Contractor
Ву	
_	Signature
	Printed Name
Tit	:le
	(AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

APPROVED AS TO CONTRACT ADMINISTRATION:

Department of Health Services

By _______ Irene E. Riley, Director Contract Administration

EXHIBIT CC

ALTAMED HEALTH SERVICES CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS)
PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED
PERSONS SEEN IN PRIMARY CARE SETTINGS
(PREVENTION WITH POSITIVES)

1. <u>DEFINITIONS</u>:

- A. Immune deficiency caused by the Human

 Immunodeficiency Virus (HIV) is a spectrum of disease

 which ranges from asymptomatic HIV disease to Acquired

 Immune Deficiency Syndrome (AIDS) as defined by the

 Federal Centers for Disease Control and Prevention (CDC).
- B. The U.S. Health Resources and Services

 Administration (HRSA) funds Special Projects of National

 Significance (SPNS) to explore HIV/AIDS care and

 treatment best practices, innovative service methods and

 system improvements. In 2003, HRSA launched a SPNS

 initiative seeking new projects to demonstrate the

 effectiveness of prevention education for people with

 HIV/AIDS in primary health care settings. Los Angeles

 County's Office of AIDS Programs and Policy (OAPP)

 received one of 15 SPNS Prevention with Positives grant

 awards nationwide.

C. "Prevention with Positives" encompasses the spectrum of prevention education activities targeting people who are HIV-positive. Providing prevention education and eliciting the involvement of HIV-positive people in the effort to stem the HIV infection rate is a key priority of the U.S. Centers for Disease Control (CDC). Prevention with Positives activities can take place in a variety of settings; the SPNS initiative focuses on the primary health care setting.

HRSA defines Prevention with Positives activities directed by the primary providers (e.g., physicians, nurses, etc.) as "provider-based", and those activities directed by others at service sites as "specialist-based". The OAPP demonstration project uses the "provider-based" model.

D. "Intervention" describes the proposed "prevention for positive" education that to be used in the new demonstration model. "Evaluation" defines those activities conducted to measure the effectiveness of the intervention. Those clinics incorporating the intervention into their regular, ongoing medical visits and participating in the evaluation are "intervention

- sites". The clinic not using the intervention, but participating in the evaluation is the "control site."
- 2. PERSONS TO BE SERVED: All HIV-positive clients receiving medical services at contracted intervention sites will be given Prevention with Positives education during their medical appointments, in accordance with directions from the project training and as described hereunder in following sections.

All contracted clinics will be required to help project evaluators identify a minimum of 150 medical clients for participation in evaluation activities, as described hereunder in following sections.

3. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period of March 1, 2004 through August 31, 2007, that portion of County's maximum obligation which is allocated under this Exhibit for participation in the SPNS-funded Prevention with Positives Demonstration Project shall not exceed One Hundred Twenty-Two Thousand, Five Hundred Dollars (\$122,500).

4. COMPENSATION:

A. County agrees to compensate Contractor for allowable reimbursable costs associated with participation in the SPNS-funded Prevention with Positives Demonstration Project, in accordance with the

budgets set forth in Schedules 67, 68, 69, and 70, attached hereto and incorporated herein by reference, as the budgetary items currently exist or as they are modified in the future by the Office of AIDS Programs and Policy (OAPP).

- B. Payment for services provided hereunder shall be subject to the provisions set forth in the REPORTS

 Paragraph of this Agreement.
- 5. <u>CLIENT/PATIENT ELIGIBILITY</u>: Contractor shall ensure that all client participants are HIV-infected and that their serostatus is documented in each client's medical record.
- 6. <u>SERVICE DELIVERY SITE</u>: During the period of this Agreement, Contractor's facility where participation in the demonstration project will be conducted is at: 5427 East Whittier Boulevard, Los Angeles, California 90022.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before moving location(s) of demonstration project participation.

7. SERVICES TO BE PROVIDED/SCOPE OF WORK: During each term of this Agreement, as specified in Exhibit CC, for purposes of participation in the Prevention with Positives Demonstration Project, Contractor will serve as one of two intervention sites to be studied. All provider sites will,

from time to time, be required to participate in projectrelated meetings and/or other events, as appropriate and
necessary. Participating as an intervention site entails the
following services and activities:

- A. <u>Trainings</u>: All relevant clinical staff will sit for 1) an initial one-half to one-day training detailing implementation of the proposed Prevention with Positives intervention, 2) a "booster" (follow-up) training approximately a month later, and 3) any "replacement" trainings necessitated and as appropriate. Contractor will provide the space for the trainings; OAPP will provide all other logistical arrangements. Trainings are expected to be completed by the project's first year.
- B. <u>Interventions</u>: Contractor shall participate in the implementation of project intervention, to include, but not limited to:
 - (1) Integration and on-going usage of prevention education/counseling messages, as detailed in the trainings, with proper consistency and at correct dosages, in the standard medical appointment with all clients;
 - (1) Use of certain materials in the intervention, such as the prescription pad and Sexual

Health Assessment (SHA), designed in collaboration with the Contractor;

- (3) Posting and disseminating project prevention education materials as appropriate for clients and preceding counseling during medical appointments, as and where appropriate in the primary care setting, and in accordance with clinic operational procedures;
- (4) In compliance with quality management obligations outlined in Exhibit CC, Contractor will ensure ongoing quality assurance efforts to confirm providers' usage of the client-level interventions in accordance with existing project concept and design methodology.

Contractor shall use the interventions for up two project years, starting in the first project year.

Contractor is free to adapt the intervention to its specific needs at the conclusion of the project intervention phase.

C. <u>Evaluation</u>: Contractor shall participate in all project evaluation activities, to include, but not limited to:

- (1) Referring appropriate clients to interviewers for recruitment into the project evaluation;
- (2) Providing adequate, private, secure space
 for interviewing and data entry, and storage (if
 required by Contractor);
- (3) Facilitating Institutional Review Board
 (IRB) process if required specifically for the
 Contractor;
- (4) Assisting with the screening and securing client consents when and wherever appropriate and possible;
- (5) Preparing and adhering to charting, documentation and other operational procedures as outlined in the project design;
- (6) Providing appropriate documentation when and where needed as required to support evaluation, data entry and subsequent analysis;
- (7) Coordinating the recruitment of Contractor personnel to participate in qualitative provider interviews;

(8) Helping to recruit clients to participate in project focus group activities, as needed and appropriate.

The project evaluation is a three-year effort and will begin in the latter half of the project's first year.

- 8. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following report(s):
 - A. Monthly Report: Contractor shall submit to OAPP a monthly report together with an invoice no later than thirty (30) days after the end of each calendar month.

 Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP.
 - B. <u>Semi-Annual</u>: Contractor shall submit to OAPP a semi-annual report within the time period as directed for each six month period. Semi-annual reports shall include all the required information and be completed in the correct format.
 - C. Annual Report: Contractor shall submit to OAPP an annual report within the time period as directed for

each year. Annual reports shall include all the required information and be completed in the correct format.

- 9. QUALITY MANAGEMENT: Contractor shall implement a Quality Management (QM) program that assesses the extent to which the care and services provided are consistent with Federal (e.g., Public Health Services and CDC Guidelines), state, and local standards of HIV/AIDS care and services. The QM program shall at a mimimum: 1) Identify leadership and accountability of the medical director or executive director, 2) Use measurable outcomes and data collected to determine progress toward established benchmarks, 3) Focus on linkages to care and support services and client perception pertaining to their health and the effectiveness of the service received, 4) Be a continuous quality improvement (CQI) process reported to senior leadership annually.
 - A. Quality Management Plan: Contractor shall base its program on a written QM plan. Contractor shall develop one agency-wide QM plan that encompasses all HIV/AIDS care and prevention services if possible. The QM plan is to be submitted to OAPP at the beginning of a contract term. The plan shall be reviewed and updated annually by agency's QM committee and signed by the medical director or executive director. QM plan and

program, will be reviewed by OAPP staff during the QM program review.

The written Quality Management plan shall at a minium include the following components:

- 1) Objectives: QM plan should delineate specific goals and objectives that are in line with the program's mission, vision and values.
- 2) OM Committee: Describes the purpose of the committee, composition, meeting frequency, at a minimum quarterly, and required documentation (e.g., minutes, agenda, sign-in sheet, etc.). A separate Committee need not be created if the contracted program has established an advisory committee or the like, so long as its composition and activities conform to the QM program objectives.
- 3) <u>Selection of a QM Approach</u>: Describes the QM approach, such as Plan-Do-Study-Act (PDSA), Chronic Care Model or Joint Commission on Accreditation of Healthcare Organization (JCAHO) 10-Step model, etc.

4) OM Program Content:

a. Measurement of Outcome Indicators - at a minimum, collection and analysis of data measured from the specific OAPP selected indicators. In

addition, contractor can measure other aspects of care and services as needed.

- b. Development of Data Collection Method to include sampling strategy (e.g., frequency,
 percentage of sample size), collection method
 (e.g., chart abstraction, interviews, surveys,
 etc.), and creation of a data collection tool.
- c. Collection and Analysis of Data results to be reviewed and discussed by the QM committee.

 The findings of the data analysis are to be communicated with all program staff involved.
- d. Identify and Sustain Improvement QM committee shall be responsible for identifying improvement strategies, tracking progress, and sustaining the improvement achieved.
- 5) Random Chart Audits (Medical Outpatient,
 Medical Nutrition, Case Management, Mental Health,
 Psychiatry, and Dental Providers of Care Services):
 Sampling criteria shall be based on important aspects
 of care and shall be, at a minimum, 10% or 30 charts,
 whichever is less. Results of sampling to be
 reported and discussed in the QM committee quarterly.

- describe the mechanism for obtaining ongoing feedback regarding service effectiveness, efficacy, accessibility, and satisfaction. Client input obtained shall be discussed at the QM Committee on a regular basis for the enhancement of the service delivery. Aggregated data is to be reported to the QM committee annually for continuous program improvement.
- 7) Client Grievance Process: Contractor shall establish policy and procedure for addressing and resolving client's grievances at the level closest to the source within agency. The grievance data is to be tracked, trended, and reported to the QM committee for improvements of care and services. The information is to be made available to QM staff during program reviews.
- B. Quality Management Program: To determine the compliant level, OAPP shall review contractor's QM program annually. A numerical score will be issued to the contractor's QM program based on 100% as the maximum score. Contractor's QM program shall be assessed for implementation of the following components:

OM Program Objectives

QM Committee

Selection of a QM Approach

QM Program Content

Random Chart Audit (if applicable

Client Feedback Process

Client Grievance Process

OAPP/SPNSALTAMED2004.ks

ALTAMED HEALTH SERVICES CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

Bud Date of Boar <u>Februar</u>	d Ar	through
Salaries	\$	21,168
Employee Benefits	\$	5,292
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$	26,460
Operational Expenses		
Indirect Cost §		
TOTAL PROGRAM BUDGET		

ALTAMED HEALTH SERVICES CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period March 1, 2005 through February 28, 2006	
Salaries	\$ 22,337	
Employee Benefits	\$ 5,584	
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 27,921	
Operational Expenses	\$ 2,891	
Indirect Cost §		
TOTAL PROGRAM BUDGET		

ALTAMED HEALTH SERVICES CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period March 1, 2006 through February 28, 2007	
Salaries	\$ 22,337	
Employee Benefits	\$ 5,584	
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 27,921	
Operational Expenses	\$ 2,891	
Indirect Cost		
TOTAL PROGRAM BUDGET \$		

ALTAMED HEALTH SERVICES CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period March 1, 2007 through August 31, 2007
Salaries	\$ 13,030
Employee Benefits	\$ 3,257
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 16,287
Operational Expenses \$	
Indirect Cost §	
TOTAL PROGRAM BUDGET \$	

ALTAMED HEALTH SERVICES CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period March 1, 2007 through August 31, 2007	
Salaries	\$ 13,030	
Employee Benefits	\$ 3,257	
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 16,287	
Operational Expenses	\$ 1,687	
Indirect Cost §		
TOTAL PROGRAM BUDGET		

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) COUNSELING AND TESTING SERVICES SERVICES AGREEMENT

Amendment No. 2

	THIS AMENDMENT	is made and entered into this day
of _		, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	CLINICA MONSENOR OSCAR A. ROMERO (hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) COUNSELING AND TESTING SERVICES AGREEMENT", dated March 26, 2002, and further identified as Agreement No. H-213466, and any Amendments thereto (hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and provide the changes set forth herein; and

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor will participate in the Los Angeles County Eligible Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of State and/or federal Centers for Disease Control and Prevention (CDC) funds, where there is a Service Provider Network (SPN) in the SPA in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must implement a "consumer advisory committee" with

regular meetings and consumer membership as a mechanism for

continuously assessing client need and adequacy of

Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must actively collaborate and recruit referrals

from service organizations and agencies beyond the Ryan White

CARE Act service delivery system, including, but not limited

to, substance abuse, mental health, primary health care and

social services organizations.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor's referrals to and from organizations must be noted

and tracked in the OAPP service utilization data system, and

followed up in client need and adequacy of Contractor's

services, and to obtain client feedback.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties hereto agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on March 26, 2002 and continue in full force and effect through December 31, 2004. Said Agreement shall thereafter be renewed for one (1) nine (9) month two (2) week term effective January 1, 2005 through September 14, 2005 subject to the availability of Federal, State or County funds. If such funding is not forthcoming, this agreement shall terminate on September 14, 2004. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. In any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, A-1, A-2, A-3, A-4, D, D-1, D-2 E, E-1 and E-2, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>,
 Subparagraphs E and F, shall be added to read as follows:
 - "E. During the period date of Board approval through December 31, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Eighty-Five Thousand, Four Hundred Fifty Seven Dollars (\$85,457). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 9, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Rapid HIV-1 AntiBody Test Services.
 - F. During the period January 1, 2005 through
 September 14, 2005, the maximum obligation of County for
 all services provided hereunder shall not exceed One
 Hundred Forty-Two Thousand, Four Hundred Twenty-Seven

Dollars (\$142,427). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 10, attached hereto and incorporated herein by reference.

Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Rapid HIV-1 AntiBody Test Services."

- 5. Paragraph 4, <u>FUNDING/SERVICES ADJUSTMENTS AND</u>

 <u>REALLOCATION</u>, Subparagraph C, shall be added to Agreement as follows:
 - "C. Funds received from the State and/or CDC will not be utilized to make payments for any item or service to the extent that payment has been made or can be reasonably expected to be made, with respect to any item or service by:
 - (1) Any State compensation program, insurance policy, or any federal, State, County, or municipal health or social service benefits program, or;
 - (2) Any entity that provides health services on a prepaid basis."
- 6. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:

- "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder on a fee
 for-service basis as set forth in Schedules 1, 2, 3, 4,

 5, 6, 7, and 8, and for actual reimbursable net cost as

 set forth in Schedules 9 and 10."
- 7. Paragraph 7, <u>CONFLICT OF TERMS</u>, shall be amended to read as follows:
 - "7. CONFLICT OF TERMS: To the extent there exists any conflict or consistency between the language of this Agreement (including its ADDITIONAL PROVISIONS) and that of any exhibit(s), Attachment(s) and Schedules(s), and any documents incorporated herein by reference, the language found within this Agreement shall govern and prevail, and the remaining exhibit(s) and schedule(s) shall govern and prevail in the following oder:

Exhibits A, A-1, A-2, A-3, A-4, D, D-1, D-2 E, E-1 and E-2

Schedules 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10, Exhibit B.

8. Paragraph 17, <u>COST REIMBURSEMENT</u>, shall be added to Agreement as follows:

- "17. <u>COST REIMBURSEMENT</u>: County shall compensate Contractor for actual reimbursable net costs incurred by Contractor in performing services hereunder.
 - A. Monthly Billing: Contractor shall bill
 County monthly in arrears. All billings shall
 include a financial invoice and all required
 programmatic reports and/or data. All billing shall
 clearly reflect all required information as
 specified on forms provided by County regarding the
 services for which claims are to be made and any and
 all payments made to Contractor by, or on behalf of,
 clients/patients. Billings shall be submitted to
 County within thirty (30) calendar days after the
 close of each calendar month. Within a reasonable
 period of time following receipt of a complete and
 correct monthly billing, County shall make payment
 in accordance with the schedule(s) attached hereto.

B. County Audit Settlements:

(1) If an audit conducted by federal,
State, and/or County representatives finds that
actual reimbursable net costs for any services
furnished hereunder are lower than the payments
made thereof by County, and/or if it is

determined by such audit that any payments made by County for a particular service is for costs which are not reimbursable pursuant to provisions of this Agreement, then the difference shall be repaid by Contractor.

- (2) If within forty-five (45) calendar days of termination of the contract period, such audit finds that the allowable costs of services furnished hereunder are higher than the payments made by County, then the difference may be paid to Contractor.
- C. In no event shall County be required to reimburse Contractor for those costs of services provided hereunder which are covered by revenue from or on behalf of clients/patients or which are covered by funding from other governmental contracts or grants.
- D. In no event shall County be required to pay Contractor more for all services provided hereunder than the maximum obligation of County as set forth in the MAXIMUM OBLIGATION OF COUNTY Paragraph of this Agreement, unless otherwise revised or amended under the terms of this Agreement.

E. Travel costs shall be reimbursed according to applicable federal, state, and/or local guidelines. Prior authorization, in writing, shall be required to claim reimbursement for travel outside Los Angeles County unless such expense is explicitly approved in the contract budget. Request for authorization shall be made in writing to Director and shall include the travel dates, locations, purpose/agenda, participants, and costs.

F. Withholding Payment:

requirements of this Agreement and the exhibit(s) attached hereto, County may withhold any claim for payment by Contractor if any report or data is not delivered by Contractor to County within the time limits of submission as set forth in this Agreement, or if such report or data is incomplete in accordance with requirements set forth in this Agreement. This withholding may be invoked for the current month and any succeeding month or months for reports or data not delivered in a complete and correct form.

- and ADMINISTRATION Paragraphs of this Agreement, and the exhibits attached hereto, County may withhold any claim for payment by Contractor if Contractor has been given at least thirty (30) calendar days' notice of deficiencies in compliance with the terms of this Agreement and has failed to correct such deficiencies. This withholding may be invoked for any month or months for deficiencies not corrected.
- (3) Upon acceptance by County of all report(s) and data previously not accepted under this provision and/or upon correction of the deficiencies noted above, County shall reimburse all withheld payments on the next regular monthly claim for payment by Contractor.
- (4) Subject to the provisions of the exhibits of this Agreement, if the services are not completed by Contractor within the specified time, County may withhold all payments to Contractor under this Agreement between County and Contractor until proof of such services is delivered to County.

- (5) In addition to Subparagraphs (1) through (4) immediately above, Director may withhold claims for payment by Contractor which are delinquent amounts due to County as determined by a cost report settlement, audit report settlement, or financial evaluation report, resulting from this or prior years' Agreement(s).
- G. Contractor agrees to reimburse County for any federal, State, or County audit exceptions resulting from noncompliance herein on the part of Contractor or any subcontractor.
- 9. Exhibit E, E-1, and E-2 SCOPES OF WORK FOR HIV/AIDS COUNSELING AND TESTING RAPID HIV-1 ANTIBODY TEST SERVICES, are attached hereto and incorporated herein by reference.
- 10. Schedules 9 and 10, BUDGETS FOR HIV/AIDS COUNSELING AND TESTING RAPID HIV-1 ANTIBODY TEST SERVICES, are attached hereto and incorporated herein by reference.
- 11. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

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Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

By ______ Thomas L. Garthwaite, M.D. Director and Chief Medical Officer

CLINICA MONSENOR OSCAR A. ROMERO Contractor

By _____ Signature

Printed Name

Title _____ (AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

APPROVED AS TO CONTRACT ADMINISTRATION:

Department of Health Services

By ______ Irene E. Riley, Director Contract Administration

EXHIBIT E

CLINICA MONSENOR OSCAR A. ROMERO

ROUTINE HIV TESTING IN CLINICAL SETTINGS USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES

- 1. <u>DEFINITION</u>: Routine HIV testing in clinical settings using the OraQuick Rapid HIV-1 antibody test services provide routine HIV testing to all individuals who visit a variety of clinical settings and meet eligibility criteria, pre- and post-test counseling, linked referrals to appropriate health and social services as needed by client, and the provision of appropriate HIV risk reduction intervention based on client's need. Such services shall be provided through urgent care facilities. For the purposes of this Agreement, a linked referral is any referral that is facilitated by the providers and confirmed as met by the referring agency. At a minimum, a linked referral must include: referral information provided in writing and verification regarding client's access to services. Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services are provided free of charge and on a confidential basis.
- 2. <u>PERSONS TO BE SERVED</u>: Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services shall be provided to individuals that meet the following criteria: (1) are at

least 12 years of age, (2) are not in critical condition, (3) are not previously known to be HIV infected, (4) are without unstable psychiatric condition, (5) are not under the influence of alcohol or other illicit drugs, and (6) are not identified as a prisoner or detainee in Service Planning Areas 1 through 8 of Los Angeles County.

- 3. COUNTY'S MAXIMUM OBLIGATION: During the period of September 15, 2003 through September 14, 2005, that portion of County's maximum obligation which is allocated under this Exhibit for routine HIV testing in clinical settings using the OraQuick rapid HIV-1 antibody test services shall not exceed Two Hundred Twenty Seven Thousand, Eight Hundred and Eighty Four Dollars (\$227,884).
- 4. <u>COMPENSATION</u>: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedules 9 and 10.

Payment for services provided hereunder shall be subject to the provisions set forth in the COST REIMBURSEMENT
Paragraph of this Agreement.

5. <u>SERVICE DELIVERY SITE(S)</u>: Contractor's facility where services are to be provided hereunder is located at:

123 South Alvarado Street, Los Angeles, California 90057 and other sites as approved by OAPP's Director.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before terminating services at such location(s) and/or before commencing such services at any other location(s). OAPP reserves the right to approve and deny all requests and will make such decisions based on the appropriateness of the request.

SERVICES TO BE PROVIDED: During each term of this Agreement, Contractor shall provide routine HIV testing in clinical settings using the OraQuick Rapid HIV-1 antibody test to persons meeting the eligibility criteria, in accordance with procedures formulated and adopted by Contractor's staff, the Centers for Disease Control and Prevention (CDC); consistent with California law; California Department of Health Services (CDHS) - Office of AIDS (OA) guidelines and the terms of this Agreement. The Director of OAPP shall notify Contractor of any revisions to OAPP policies and procedures, which shall become part of this Agreement. Pretest and disclosure counseling shall follow Los Angeles County guidelines for HIV Prevention Counseling as adopted by the Centers for Disease Control and Prevention (CDC) and CDHS-OA. All counseling sessions shall take place in a private, faceto-face session in a closed room or area that ensures patient confidentiality. Additionally, Contractor shall provide such

services as described in Exhibits E-1 and E-2, Scopes of Work, attached hereto and incorporated herein by reference.

Minimum services to be provided shall include, but not be limited to, the following:

- A. Provide Confidential testing upon acceptance by client. Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. For those clients who whish to only be tested anonymously, a referral to an anonymous counseling and testing site shall be provided.
- B. Provide a client-centered counseling session that engages the client in a dialogue that encourages the disclosure of unique individual needs and concerns related to HIV risk and emphasizes personal options that limit or prevent transmission of HIV. Additionally, the client-centered counseling session should accomplish the following: a) improve the client's self-perception of risk; b) support behavior change previously accomplished or attempted by the client; c) negotiate a workable short-term and long-term risk reduction plan based on the client's perceived ability to change his or her behavior; d) support informed decision-making about whether to be

tested; e) obtain informed consent; f) obtain consent to draw a confirmatory test specimen in the event that the rapid test result is preliminary positive; g) review the nexus between HIV and STD infections; h) ensure that the client understands the meaning of test results, including a reactive OraQuick result requiring confirmatory testing; and i) assess the client's potential reaction to receiving a reactive rapid test. The Contractor shall fully collect client demographic information using the handheld computer system using iPAQ Pocket PCs provided by OAPP. All information reported on the approved device(s) and lab slips shall be voluntarily supplied by the client. In the event that the PDA device is not working appropriately, or the individual feels uncomfortable with the use of the PDA, a paper based data collection instrument will be made available to continue the pre-test counseling session. In the even that client level data is collected on the paper-based data collection tool, the information will be entered into a PDA prior to submission of all client level data to OAPP. Once received at OAPP, the client level data will be submitted to CDC based on their schedule of data submission.

- 7. Provide an FDA-approved Rapid HIV-1 antibody test to determine the presence of HIV antibodies. The provision of screening procedures shall be preceded by a review with the client of the following areas: a) information regarding risks and benefits of the Rapid HIV-1 antibody test; b) an explanation of the meaning of the respective test results; c) an explanation of the respective testing procedures; d) information on the importance of a confirmatory test if the test result is preliminary positive; e) a review of the HIV-antibody window period; and f) completion of OAPP-approved consent form signed by the client and maintained in the client's file in accordance with the California Code of Regulations.
 - A. The HIV Certified Counselor shall ensure to follow the steps to testing using the OraQuick rapid HIV-1 antibody test as delineated in the OraQuick package insert and in the Step-by-Step Instructions for OraQuick Rapid HIV-1 Antibody Test.
 - B. Conduct a client-centered disclosure counseling session that serves to provide the client with their results and that integrates the test result in a meaningful and productive manner based on their reported risk factors and consistent with their risk reduction

efforts. Test results shall not be mailed, nor disclosed over the phone, nor given to anyone except the client, nor given in the presence of other persons with the exceptions stipulated by California Health and Safety Codes 121010, 121015, 121020, 120975, 120980, and 120985.

The HIV Certified Counselor reviewing the client's Counseling Information shall precede the disclosure session. The HIV Certified Counselor personalizing and framing the session to the client to establish a comfortable setting by describing disclosure session steps shall precede the disclosure event. HIV Certified Counselor shall disclose the results, review the medical interpretation of the test result and assess the client's emotional state, counseling needs, understanding of the test results, need to be re-tested based on the window period and recent risk behaviors, need to test for a confirmatory test for preliminary positive results. The HIV Certified Counselor shall assess the client's understanding of and commitment to risk reduction quidelines as well as the strength of social support and plans for and consequences of disclosure to others.

- D. For clients testing HIV-positive, the following additional topics shall be covered in the disclosure session; a) need for a confirmatory test, b) information regarding the risk of HIV transmission to the fetus or newborn during pregnancy, during labor and delivery, and during the postpartum period if the individual is a woman or the male partner of a women of childbearing age; c) information on the risks of re-infection; d) written documentation of information and/or assistance with partner notification and/or linkage to Los Angeles County Department of Health Services Partner Counseling Referral Services (PCRS) and field follow-up services for assisted partner notification; e) a written assessment of the client's reaction to the positive test result to determine whether referral for psychosocial support services, including suicide prevention, is indicated.
- E. The HIV Certified Counselor shall assess the need for referrals and provide specific, written referrals with adequate linkages as appropriate. At a minimum, referrals to the following services shall be considered based on client risk and test results: risk reduction, prevention for HIV-infected persons, mental health services, partner counseling and referral

services, and tuberculosis screening and drug treatment services. For HIV-positive clients written referrals to a minimum of three (3) primary medical care providers shall be provided and any other linked referrals appropriate to the immediate health and social needs of the client. The Contractor shall document all linked referrals and referral follow-up for each person served under this Agreement. The linked referral follow-up shall include, but not be limited to, the agency the person was referred to, any appointment(s) made, no show for said appointment, and follow-up plan, if the individual failed to show for confidential testing.

- F. Contractor shall comply with the Interim
 Revision of Requirements for Content of AIDS-related
 Written Materials, Pictorials, Audiovisuals,
 Questionnaires, Survey Instruments, and Educational
 Sessions in Centers for Disease Control Assistance
 Programs, as referenced in Exhibit B.
- G. Contractor shall obtain written approval from OAPP'sDirector for all educational materials utilized in association with this Agreement prior to its implementation.

- H. Contractor shall submit for approval such educational materials to OAPP at least thirty (30) days prior to the projected date of implementation. For the purposes of this Agreement, educational materials may include, but not limited to, written materials (e.g., curricula, pamphlets, brochures, fliers), audiovisual materials (e.g., films, videotapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings).
- I. Failure of Contractor to abide by this requirement may result in the suspension of this Agreement at the Director's sole discretion.
- J. Contractor shall utilize funds received from County for the sole purpose of providing HIV/AIDS counseling, testing, immune assessment, and referral services.
- K. Contractor shall not utilize funds received from County for the purpose of any and all activities associated with needle exchange, including, but not limited to, purchasing and exchanging of needles.
- L. Contractor shall ensure that all staff supported by County funds are not engaged in any and all needle exchange activities.

- M. Contractor shall be responsible for reimbursing County for all funds expended on any and all activities associated with needle exchange.
- N. Any breach of these provisions shall result in the immediate termination of agreement.

8. ADDITIONAL REQUIREMENTS:

A. Offering HIV Counseling and Testing: HIV counselors shall routinely offer HIV rapid testing through two mechanisms: (1) a sampling pattern of every 3rd person to be selected from the clinic registration/sign-in sheet. This log shall contain at a minimum, the client's name and reason for visit; (2) clinician-initiated referrals for routine screening shall be made. A waiting list shall be established at each site to appropriately queue clients who have been offered and are interested in receiving an HIV rapid test. In the event that the HIV counselor is unavailable, clinician-initiated referrals shall be added to the waiting list. First priority will be given to those clients signed up on the waiting list. Educational posters, pamphlets and brochures describing HIV counseling and testing (specifically through the use of a

rapid test), and general HIV risk information will be made available.

B. HIV counselors shall approach prospective testers and in the discretion of a private counseling room, offer a routine HIV rapid test. The counselors shall identify themselves as facility staff and inform the potential tester that routine HIV rapid testing is being made available to any individual seeking services. The counselors shall briefly explain the following:

(1) The HIV testing process:

- (a) The use of an OraQuick® rapid HIV test.

 Only confidential testing shall be offered.

 Referrals shall be provided to other clinics offering anonymous HIV testing. Counselors shall discuss the following: (1) the difference between a standard blood test, an OraSure-oral (OMT) test, and the rapid test; (2) the type and method of specimen collection; (3) the waiting time for results; (4) what different results mean; and (5) confirmatory testing.
- (b) Upon brief discussion of these topics, the counselor shall confirm the individual's willingness to discuss HIV rapid testing. Upon

consent (both verbal and written), the counselor will engage the client through the standard pretest counseling and informed consent process.

(2)Individuals Refusing HIV Counseling and Testing: Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of nonrespondents can be evaluated. Some individuals may not wish to discuss HIV counseling and testing because they are already HIV positive. In these cases, counselors shall determine if the individual is receiving medical care for his/her HIV infection, as well as provide referrals for services, including additional medical care services, and other community and psychosocial services. If a need for such services is identified, the individual will be referred to the appropriate service provider. Referrals for medical care, social services, and mental health will be made available to all clients regardless of their decision to test. HIV counselors shall use the iPAQ Pocket Personal Computers (PDA) to collect refusal information and they will also document refusal to test in the

medical record. This will ensure that negative clients who refused HIV testing are offered testing again during their next clinic visit. Linkages to non-HIV medical care and delivery of referrals shall continue regardless of the client's desire to test or not. For individuals who do not wish to consider HIV counseling and testing for reasons other than a prior HIV diagnosis, the reason for their refusal should be elicited to evaluate potential bias.

Testing: Individuals who meet the established eligibility criteria and consent to test, shall be tested for HIV using the OraQuick® rapid HIV test.

For the purposes of this agreement only confidential tests may be performed so that follow-up for provision of medical and psychosocial services may be accomplished. Clients who wish to test via an anonymous test shall be directed to other testing facilities where an anonymous test may be obtained.

All HIV counselors providing services through this project are certified HIV test counselors, trained and certified phlebotomists, and trained in Rapid HIV counseling and testing. All pre- and post-test

counseling, specimen collection, data collection and disclosure will take place in a room or space that ensures appropriate confidentiality and privacy.

All counselors will provide HIV rapid testing in accordance to OraQuick® HIV rapid test guidelines.

The following steps will be conducted for each individual being tested for HIV:

(a) Pre-test Counseling and Consent to Test: The HIV counselor will conduct a pre-test counseling session which consists of providing the client with information required to make an informed choice regarding HIV testing. It also offers an opportunity for discussion with the client regarding their reasons and feelings related to HIV testing, meaning of test results, and transmission risks. During this session, the counselors shall explain the following: (1) The differences and methods of standard testing (serum and/or oral fluid) and OraQuick® testing; (2) the procedures related to each of the testing options, such as how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat

testing; and (3) relevant information regarding the window period. Counselors must be clearly explain that the OraQuick® rapid test only refers to obtaining results rapidly-not to reducing the time between exposure and identification of infection. If a client has had a recent exposure (less than 3 months) and their test is non-reactive, the client shall be counseled to re-test at 3 months from exposure. If the client decides to be tested with OraQuick®, counselors will: (1) ensure that the client understands the meaning of test results, including that a reactive OraQuick® result requires confirmatory testing; (2) assess client's potential reaction to receiving a reactive rapid test; (3) informed consent must be provided for confidential HIV testing according to local standards. The consent form shall also request a commitment for collection of a second specimen (serum or oral fluid) for individuals testing preliminary positive via OraQuick®. In addition, all counselors shall be required to follow local guidelines and

recommendations pertaining to HIV counseling and testing, HIV rapid testing, and Phlebotomy (both venipuncture and finger stick).

- (b) If the HIV counselor is not certified in phlebotomy or providing finger sticks, they shall escort the client to the appropriate medical or laboratory staff for a finger stick.

 Once the blood specimen is collected, the counselor shall ensure the test is processing accurately, and will return the client to the counseling room for continuation of the pre-test counseling session.
- (c) Once the tests are fully run

 (approximately 20-40 minutes after initial blood sample is collected and placed in the testing mechanism), the counselor shall return to the laboratory (or designated testing room) to obtain the test results. The counselor shall return to the private counseling room to disclose the test results to the patient.

C. <u>Materials Required for Testing</u>:

(1) The following materials are provided to the site: (1) The OraQuick® Rapid HIV-1 Antibody Test packaged in a divided pouch that contains the device (with absorbent packet) in one side and the developing solution in the other; (2) reusable test stands; (3) specimen collection loops; (4) subject information pamphlets; (5) package insert; and (6) external controls (set of positive and negative).

The following materials are not provided to (2) the site but are required. Agencies must have all of these materials prior to conducting testing; (1) latex, vinyl or nitrile disposable gloves; (2) sterile retractable lancets; (3) timer or watch capable of timing 20-60 minutes; (4) clean, disposable, absorbent workspace cover ("chux" pads); (5) antiseptic wipes; (6) sterile gauze pads (2"x2"); (7) small adhesive bandages; (8) bio-hazard sharps container and trash bags; (9) surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide); (10) alcohol-based waterless hand cleanser; (11) laboratory grade thermometers to measure storage temperature of test devices and controls and temperature of testing location; (12) required forms; and (13) a flashlight to illuminate

the result window in case the result is difficult to read.

- (3) Conditions for Testing: The following conditions must be present to use OraQuick®:

 (1) sufficient lighting to safely and accurately perform the test and read the result; (2) a level, clean surface where testing can be performed; (3) temperature of the test kit and test area shall be between 59° and 80° Fahrenheit; and (4) space that assures confidentiality for both testing and counseling.
- utilize external controls that verify whether the devices are working properly or staff are properly performing the test. Each set consists of two vials, a positive control and a negative control. The positive control (the black cap) contains a serum-based solution containing antibodies that will show a reactive result when used with the OraQuick® test. The negative control (the white cap) will show a non-reactive result when tested. If the device does not show the expected result when each

control is used, either the test was not performed properly or the device is defective.

- under the following conditions: (1) when a staff person has been trained to conduct OraQuick® testing, prior to testing client specimens; (2) when a new box of test kits is opened at the testing site; (3) when testing conditions change: lighting, temperature, unusual environmental conditions, etc; (4) if the temperature of the test kit storage area falls outside 35°-80°F; (5) if the temperature of the testing area falls outside 59°-80°F; and (6) external controls should be conducted at least once every 25 tests or once a month, whichever occurs first.
- (b) The external controls must be refrigerated (temperature must be between 35°-46° F). Controls do not need to be warmed to room temperature prior to use. Although the controls have an expiration date that is one year post-production, once controls are opened they <u>must</u> be used within 3 weeks. Controls

shall be dated when they are opened and discarded 3 weeks after this date. Staff may record on a refrigerator log when controls should be disposed.

- D. Testing Steps: The following is a summary of the steps required to complete an OraQuick® test. More detailed instructions are delineated in the OraQuick® package insert and in the Step-by-Step Instructions for OraQuick® Rapid HIV-1. Counselors must familiarize themselves with both of these resources prior to testing clients.
 - absorbent cover. Place stand, divided pouch, loops, antiseptic wipes, sterile retractable lancet, disposable gloves, sterile gauze, and bandages at workspace. Check expiration date of packet. If expired, dispose and obtain a new pouch that is not expired. Check to make sure there is an absorbent packet in the device side of the pouch. If none is present discard the entire pouch and obtain a new one. Open the two chambers of the divided pouch and label the test device and the developer solution vial with the client's project ID number. Keep the

paddle end of the device inside the package to avoid contamination. Do not cover the holes on the back of the device. Remove the cap from the vial and slide it into the stand from the top. Place the cap on the absorbent cover near the stand. Put on disposable gloves.

- (2) Collection: Clean the client's finger with an antiseptic wipe and allow it to dry thoroughly.

 Using a sterile retractable lancet, puncture the skin just off the center of the finger pad. Discard lancet in a sharps container. Allow a drop of blood to form and wipe it away with sterile gauze. Allow a second drop of blood to form and place the loop onto this drop. Make sure the blood fills the inside of the loop.
- (3) Mixing: Insert the loop into the vial being careful not to touch the loop to the sides of the vial. Stir the solution with the loop to properly mix. Discard the loop in a waste container. Make sure the solution appears pink.
- (4) Testing: Remove the device from the pouch.

 Do not touch the Flat Pad. Insert the Flat Pad end

 of the device into the developing solution with the

result window facing forward. Note the starting time on the testing log. Read the result of the test after 20 minutes but not more than 40 minutes from the time the device was placed in the solution.

- (5) Reading the result: A valid test result must have a reddish-purple line next to the "C" (Control) triangle. If no line is present at this area, the test is invalid and no result can be interpreted. In this case, the client must be tested again. A line at only the "C" triangle, and no line at the "T" (Test) triangle, is interpreted as a non-reactive or negative test result. client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client should be retested 3 months after the exposure. Lines at both the "C" and "T" area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen from the client to determine whether the client is infected with HIV.
- (6) Assessing Invalid Results: To assess why a test may be invalid, staff shall review procedures to determine that the test was conducted properly. A

second test shall be conducted. If this test is also invalid, external kit controls shall be run. If the expected results are not obtained, staff shall contact the appropriate project director for their site. If it appears that devices are defective, the OraSure® customer service department should be contacted at 1-800-672-7873. Testing with the OraQuick® rapid HIV-1 antibody test shall be halted until it is determined if the invalid results are due to a faulty lot of test kits.

- (7) Documentation of the Result: The OraQuick® rapid test results shall be recorded in the handheld data collection device. For individuals testing preliminary positive, contact information should be collected so that they may be re-contacted to receive a confirmatory test result. The project identification number and contact information shall be documented in a log book (see Data Collection Procedures below).
- (8) Clean up: Dispose of retractable lancets in a sharps container and all other used test materials (capped vial, device, loops, used gauze and gloves, etc.) in a trash bag. Clean any spills

with a surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide). Remove gloves and wash hands after every test is performed. Use new gloves for each client.

- F. Confirmatory Testing: All clients receiving a reactive (Preliminary Positive) OraQuick® result should immediately have a specimen collected for a confirmatory test to determine whether they have HIV infection. All clients consenting to test, will be asked for an additional confirmatory specimen, in the event that their rapid test is preliminary positive. A serum or oral fluid specimen will be obtained from the client and sent to a laboratory for Western blot testing.
- G. Disclosure of Preliminary Positive (Reactive)
 Results: The following information shall be covered when providing post-test counseling to someone with a reactive OraQuick® result. Throughout this process, counselors shall provide emotional support to assist the client to cope while waiting for the confirmatory test. The client advocates will play a crucial role in ensuring that the clients keep their scheduled confirmatory test disclosure sessions.

- (1) Disclosure: The test counselor will: (1) interpret the result and assess client understanding of the result; (2) explain confirmatory testing; (3) obtain commitment from client to return for confirmatory result; (4) discuss what client intends to do during waiting time, including disclosure issues; (5) encourage client to take precautions to avoid potentially transmitting the virus to others; (6) assess need for referrals; and (7) interpret the result and assess client understanding of the result. Reactive results are defined as "preliminary positives" by the Centers for Disease Control and Prevention (CDC).
- confirmatory testing: A specimen for confirmatory testing shall be obtained immediately for Western blot testing. If possible, a blood specimen should be drawn. If the counselor does not perform phlebotomy, an oral fluid specimen can be obtained. Counselors shall inform clients that if the confirmatory test result were negative, a second confirmatory test, a serum test, would be done to be absolutely certain that they are not infected.

 Counselor shall obtain commitment from client to

return for confirmatory result. Counselors shall set an appointment with the client in to receive the confirmatory test result. All confirmatory results should be provided in person to facilitate linkage to further services and provision of emotional support. Counselor shall discuss what client intends to do during waiting time, including disclosure issues. Counselors shall discuss how clients intend to cope during this waiting period and who, if anyone, they intend to tell about their rapid test result. Counselor shall encourage client to take precautions to avoid potentially transmitting the virus to others. Counselors shall encourage and support the client in use of risk reduction behaviors to avoid potentially transmitting the virus to others. This includes examining the client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.

(3) Assess need for referrals: At a minimum counselors shall offer to be a support to the client via phone or in person. In addition, referrals to a mental health counselor, risk reduction specialist,

or crisis line shall be provided as needed by the client. A description of partner counseling and referral services, as well as access to medical care, legal services, case management, and the drug reimbursement or health insurance programs should be provided to clients testing preliminary positive.

- interpreted as negative unless the client has engaged in risk behavior within the last three months. If the client has engaged in risk behavior during this time, counselors shall recommend a retest three months after their last exposure.

 Counselors shall assess for additional services needed by the client, such as STD or hepatitis testing, alcohol and other drug abuse treatment, economic assistance, domestic violence services, housing, etc.
- H. Disclosure of Confirmed Positive Results: The following information shall be covered when providing post-test counseling to someone with a confirmed positive HIV test result. Throughout this process, counselors shall provide emotional support to assist the client to cope with their HIV diagnosis. In addition, each site

shall call upon their designated case manager or social worker to assist in the provision of positive results, who shall serve as client advocates and offer post-disclosure services that may include emotional and community support, information/assistance regarding identification and entry into medical care, PCRS services, medical and community linked referrals, and follow up.

I. Client Advocates: Linking clients with appropriate medical and psychosocial referrals is a key component of this project. In order to establish a continuum of care for each client, sites will use client advocates (case managers, social workers, HIV counselors, clinicians) for each client identified as high-risk negative or preliminary positive. Once the determination has been made that a client is high-risk negative or preliminary positive, or confirmed positive, the client advocate shall facilitate the referral process and provide follow up. The client advocate will continue to provide referrals to the client, in conjunction with an ongoing needs assessment, for appropriate referral sources and follow up. The client advocates shall work to ensure the clients keep their confirmatory test

disclosure appointment. Contractor shall ensure that all linkages to care, including the sharing of referral information between agencies activities, are HIPPA compliant.

- J. Linking Clients with Referral after Rapid
 Testing: Through coordination with the LA County's Office
 of AIDS Programs, and the local network of Care
 providers, OAPP staff and Epidemiology Unit will be able
 to access the IMACS/Casewatch for client registration
 information, as well as clinical diagnostic measures.
 Access to the IMACS/Casewatch system shall allow for
 collection and evaluation of post-diagnostic clinical
 information including patient viral load, T-cell count,
 etc. Consent to review this information will be obtained
 when the client enrolls in medical care services.
- K. Linked Referrals: Client advocates and clinic staff shall be charged with providing each willing client with linked referrals. Client advocate shall provide the client with information regarding appropriate resources and contact information for each referral source. The client advocate shall assess the client's immediate need for psychosocial, medical and mental health. The client advocate shall help determine what referral services are

appropriate for the clients, including referrals within the project site, or out to other local service providers. When same-day services are an option, the client advocate has three options: (1) in sites that have testing services with on-site or nearby referral services, the client advocate should walk the client to the referral source and introduce the client to the referral service provider; (2) in sites that do not have on-site referral sources, or for sites that provide rapid testing in the field, client advocates should provide transportation services for the client advocate to the referral service provider; and (3) when same-day services are not an option for referral sources, client advocates should contact the appropriate referral service provider(s) and schedule an appointment for the client. When possible, the client advocate shall accompany the client to the scheduled appointment. If this is not possible, the client advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

L. Result of the Confirmatory HIV Test:

Confirmatory Western Blot HIV test results shall be ready
within 1-2 weeks. All LA County OAPP contracted project

sites will follow local protocols for reporting Western Blot HIV positive results to local and CDC surveillance. The process for providing results begins with the client's appointment for results. If the client does not make their appointment to obtain results of the confirmatory test, the client advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate shall follow the test result protocol as explained below. When the client keeps their appointment for confirmatory test results, the client advocate shall provide confirmatory test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. In addition, the client advocate shall refer the client to medical services and reassess the client for psychosocial services. The client advocate shall determine whether or not they could obtain referral services for the client that day. If same day services are an option, the client advocate has the same three options as described. client does not make their appointment for referrals services, the client advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate should

follow the steps outlined in the Monitoring Care Services.

- Monitoring Care: Client advocates through each project site will work to follow up on clients to determine if they have entered medical care. OAPP staff shall work with project site staff to monitor local surveillance data to identify CD4 counts and viral load This process should begin three to six months after the client's appointment for confirmatory results to allow sufficient time for the client to enter care and for the lab reports to be entered into the surveillance Periodic review of IMACS/Casewatch should occur until a CD4 count and/or viral load is recorded. client advocate shall record the appointment status (missed/kept). If the appointment was missed, the client advocate shall record the type and number of attempts to contact the client. If the appointment was kept and the lab reporting data is in the system, the client advocate shall record this data.
- N. Western Blot HIV-Negative Test Result: If the client does not make their appointment to obtain results of the confirmatory test, the client advocate should follow the Lost to Follow Up Protocol. If the client is

located after following this protocol, the client advocate should follow the test result protocol. the client keeps their appointment for confirmatory test results, the client advocate should provide negative test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the client advocate should instruct the client to return for testing in one month, due to the discordant results between the OraQuick® rapid HIV test and the Western blot. The second Western Blot test shall be a standard serum HIV test, not an oral fluid test. In addition, the client advocate shall reassess the need for psychosocial services. The client advocate shall then determine whether or not they could obtain referral services for the client that day. If same day services are an option, the client advocate has three options as described above.

O. Western Blot Indeterminate Result: If the client does not make their appointment to obtain results of the confirmatory test, the client advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the client advocate should follow the test result protocol. When the client keeps their appointment for confirmatory test results, the

client advocate shall provide indeterminate test results according to the CDC Revised Guidelines for HIV

Counseling, Testing and Referral. At this time the Client Advocate shall recommend that the client seek additional HIV testing in one month, due to discordant results due to the discordant results between the OraQuick® rapid HIV test and the Western Blot. The second Western Blot test shall be a standard serum HIV test, not an oral fluid test. In addition, the client advocate shall reassess the need for psychosocial services. The client advocate shall determine whether or not they could obtain referral services for the client that day. If same day services are an option, the client advocate has three options as described previously.

9. CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS:

Contractor shall fully comply with the Subcontracting

Paragraph of the ADDITIONAL PROVISIONS section of this

Agreement. In addition, the Contractor shall ensure that

subcontractors and consultants providing services under this

Agreement shall commence services within ninety (90) days of

the execution of this Agreement, or as otherwise approved by

OAPP. Subcontract and consultant agreements shall be signed

and dated by the Contractor's Director, or his/her

designee(s), prior to commencement of subcontracted and/or consultant services.

- 10. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit:
 - A. A monthly written report together with Data

 Report no later than thirty (30) days after the end of
 each calendar month. Monthly reports shall clearly
 reflect all required information as specified on the
 monthly report form provided by OAPP. Such written
 monthly report and data report shall be mailed or
 delivered together with an invoice to Office of AIDS

 Programs and Policy, 600 South Commonwealth Avenue, 6th
 Floor, Los Angeles, California 90005, Attention:
 Financial Services Division.
 - B. Quality Assurance for the OraQuick® Rapid HIV-1
 Antibody Test, Program Monitoring and Data Collection
 (procedure for all clinics). LA County OAPP's Data and
 Epidemiology unit provides quality assurance for all OAPP
 contracted counseling and testing. This includes
 provision of technical assistance, ordering and delivery
 of supplies, and ordering controls. The Data and
 Epidemiology unit also facilitate the collection of data

for all HCT services throughout Los Angeles County, and will manage the data for this project. All participating project sites will submit the client level data (PDA data) to the Data and Epidemiology Unit for management, The Data and centralization and dissemination. Epidemiology unit will submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP will conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will be asked to report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites will be incorporated into the existing monitoring schedule for all OAPP contracted programs.

11. PROGRAM RECORDS: Contractor shall maintain and/or ensure that its subcontractor(s) maintain adequate health records which shall be current and kept in detail consistent with good medical and professional practice in accordance with the California Code of Regulations on each individual client. Such records shall include, but shall not be limited to: the

dates of the HIV risk assessment session and the disclosure session, signed consent forms for confidential tests, test results, client interviews, progress notes documenting referrals provided, and a record of services provided by the various personnel in sufficient detail to permit an evaluation of services. The program records shall also include documentation of client demographic information and the statistical summary reports submitted monthly to OAPP. A current list of service providers for medical, psychosocial, and other referral resources shall be maintained.

Contractor shall maintain additional program records as follows: a) letters of OAPP approval for all materials utilized by the program; b) documentation of staff job descriptions, resumes, and certificates and/or letters of completion of HIV Antibody Four-Day Counselor Certification Training, One-Day Re-certification Training, Three-Day PCRS certification and re-certification training, Two-Day Rapid HIV-1 Antibody Testing certification, as well as, selected STD and HIV training as attended; and c) documentation of an annual written evaluation of employee's performance and that completed evaluation has been discussed with employee. This annual evaluation shall include, but is not limited to documentation of written bi-annual observations of the

counseling session, evaluation of counselor knowledge, skills and competence to provide HIV/AIDS counseling, testing and immune assessment, and referral services.

- 12. PROGRAM EVALUATION: Contractor shall assess the program's quantitative and qualitative aspects. The initial program assessment shall be conducted three (3) months following approval of this Agreement; a second assessment shall be conducted six (6) months after approval of this Agreement. The program assessments shall include:
 - A. A review of the accuracy and appropriateness of the content of the counseling sessions and the educational materials provided.
 - B. Observation and written evaluation of the counselors on a biannual basis. Notes on the counselor's performance and the feedback given to the counselor will be included in his/her employee record.

Following the assessments, the Contractor shall report to OAPP on the program's progress and any problem areas following each assessment.

13. <u>ADDITIONAL STAFFING REQUIREMENTS</u>: The Routinely recommended HIV testing in Clinical Settings using the OraQuick Rapid HIV-1 Antibody test services shall be provided by individuals who are appropriately trained, qualified, who

meet the guidelines set forth by the CDC and are linguistically and culturally appropriate. All HIV testing and disclosure counseling sessions shall be conducted by HIV Certified Counselors trained by the CDHS-OA and/or OAPP. All HIV Certified Counselors must attend an annual one-day HIV recertification training approved by OAPP.

- A. In addition to certification and re-certification training, Contractor shall conduct ongoing appropriate staff training. All staff is required to obtain a minimum of 16 hours of continuing education units (CEU) per each term of this agreement in addition to the required recertification training. The required CEU training shall include, but is not limited to, Hepatitis B and C, STDs (including chlamydia, gonorrhea and syphilis), substance abuse and PCRS training.
- B. All testing unit staff providing direct services shall attend in-service training on substance abuse knowledge, substance misuser sensitivity, cultural approaches and substance misuse related issues, as directed by OAPP under the guidelines of the State Department of Alcohol and Drug Programs.
- C. Contractor shall document training activities in the monthly report to OAPP. For the purpose of this

Agreement, training documentation shall include, but are not limited to: date, time and location of staff training; training topic(s), name of attendees and level of staff participation.

- D. All HIV Certified Counselors providing direct services shall be sensitive to the needs of persons of diverse life experiences including, substance users, persons with mental illness, transgenders, multiply-diagnosed individuals, etc.
- E. The Project Coordinator shall be appropriately trained and knowledgeable and demonstrate a high level of competency with respect to HIV/AIDS testing and counseling issues, STD and Hepatitis C Screening, substance misuse, community referrals, and education services. The Program Coordinator shall complete the CDHS-OA and/or OAPP's HIV Counselor Certification Training and/or comparable training as approved by OAPP.
- F. Staff vacancies shall be advertised in a local newspaper and/or posted at facilities throughout Los Angeles County and/or through other methods where persons with appropriate knowledge and competency can be identified. Individuals with a history of alcohol and/or drug abuse histories who are being considered for a

counselor position shall have a minimum of two (2) years sobriety.

- G. Contractor shall participate in quarterly project meetings or as directed by OAPP.
- H. Contractor shall participate in all project conference calls.
- I. Contractor shall designate one person on staff as the key person for all data collection activities related to this agreement. Said staff shall be able to represent contractor on all issues related to data collection and the evaluation thereof.

Director shall notify Contractor of any revision of these quidelines, which shall become part of this Agreement.

14. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of service(s) and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of a tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening." Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

- approved Quality Management (QM)plan. The QM plan shall describe the process for continually assessing the contractors program effectiveness in accomplishing contractor mission, goals, and objectives. The plan shall describe the process for the following components: QM Committee, Written Policies & Procedures, Client Feedback, Program Staff, Measurable Program/Service Quality Indicators, QM Plan Implementation, and Quality Assessment & Improvement Reports.
 - A. Quality Management Committee: The QM Committee shall develop, review, and revise the agency's QM plan on an annual basis and continually assess and make recommendations for the improvement of program services. The Committee shall be responsible for developing plans of corrective action for identified program deficiencies and consist of persons that reflect the group and/or groups to whom services are targeted including clients, volunteers, program staff, management staff, consultants, staff from other community-based organizations, etc. The

Program Coordinator and a client receiving services under this contract must be included as Committee members.

Committee membership shall be described by name, title, or role, and the constituency represented (i.e., staff, management, and client). The Contractor shall review the Committee recommendations and ensure recommendations are appropriately implemented. A separate Committee need not be created if the contracted program has an established an advisory committee or the like, so long as its composition and activities conform to the criteria described in this Agreement. The QM Committee activities shall be documented. Required documentation shall include but not be limited to agendas, sign-in sheets, QM Committee meeting minutes (including date, time, topics discussed, recommendations, and corrective actions).

B. Written Policies and Procedures: Policies and procedures shall be based on essential program activities and community and professional standards of care specific to this contract. The QM Plan shall describe the process for reviewing and modifying written policies and procedures. In addition, the plan shall specify the policies be reviewed at a minimum of once a year,

approved and signed by the Executive Director or designee.

- C. Client Feedback: The QM Plan shall include a mechanism for obtaining ongoing feedback from program participants regarding program effectiveness, accessibility and client satisfaction. Describe the method(s) to be used for client feedback, (e.g., satisfaction surveys, focus groups, interviews, etc). Client feedback shall be collected on an ongoing basis or at a minimum of quarterly. Describe how client feedback data will be managed by the QM committee and used to make improvements to the program.
- D. Program Staff: The QM plan shall describe the process for developing, training and monitoring staff.

 This description shall include minimum qualifications for each program staff position and a description of the methods and instruments to be used to monitor staff performance. The QM plan shall specify that staff is evaluated annually.
- E. Measurable Program/Service Quality Indicators:

 Measurable quality indicators are intended to address how

 well services are being provided. By developing a set of

 indicators specific to each program, establishing a

measurable minimum standard for each indicator, and conducting an assessment on the extent to which the indicator is met, the Contractor shall assess the quality of service delivery on an ongoing basis. The QM Committee is responsible for developing a plan of corrective action to address any program quality deficiencies or to improve the effectiveness demonstrated by each indicator. Quality indicators shall be based on key activities described in the SERVICES TO BE PROVIDED Paragraph of this Exhibit. The QM Plan shall require measurement of and include at a minimum the following measurable program and/or services indicators:

(1) Process: Eighty-five (85%) test acceptance rate for clients approached for rapid testing; eighty-five percent (85%) post-test disclosure rate; one hundred percent (100%) HIV preliminary tests completing a confirmatory test; eighty percent (80%) of clients accepting referral counseling will be linked to appropriate levels of care services; follow-up services will be conducted for one hundred percent (100%) of clients testing preliminary positive.

- (2) Outcome: Eighty percent (80%) of clients receiving Rapid Testing services will report satisfaction with Rapid Testing services they received; seventy-five percent (75%) of clients receiving services will successfully demonstrate or discuss at least one risk reduction skill or plan.
- F. <u>QM PLAN IMPLEMENTATION</u>: Contractor shall implement its QM plan to ensure the quality of the services provided are assessed and improved on a continuous basis.
- G. Quality Assessment and Improvement Reports: The QM Plan shall include the requirement for two (2) Quality Assessment and Improvement Reports. These reports shall be developed by the QM Committee and signed by the Executive Director. Contractor shall make the following reports available to the OAPP Program Manager at the time of the monitoring review or upon request:
 - (1) Mid-Year Report shall document program performance, results of plans of corrective action, areas of concern identified by the QM Committee, and data collected from client feedback.
 - (2) Year-End Report shall document actions addressing the findings of the Mid-Year reports and

the overall program performance from Mid-Year to Year-End.

evaluation plan developed by the CDC. The pan is designed to demonstrate project accomplishments and monitor areas during the course of the project in order to improve the project's success. Evaluation measure shall include, but not be limited to: (1) number of individuals approached for rapid testing; (2) number of individuals who agree to HIV testing and other types of HIV testing; (3) number of individuals who receive rapid HIV test and confirmatory results; (4) number of HIV infected persons newly detected through rapid testing who enter into medical care; and (5) number of HIV negative persons receiving psychosocial service referrals. Contractors shall provide counseling and testing data for 2002 and 2003 for comparison purposes.

SCHEDULE 9

CLINICA MONSENOR OSCAR A. ROMERO

ROUTINE HIV TESTING IN CLINICAL SETTINGS USING THE ORAQUICK RAPID HIV-ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

Budget Period

Date of Board Approval through December 31, 2004

Salaries	\$ 58,353
Employee Benefits	\$ 15,755
Total Salaries and Employee Benefits	\$ 74,108
Operating Expenses	\$ 3,938
Capital Expenditures	\$ -0-
Other Costs	\$ -0-
Indirect Costs	\$ 7,411
TOTAL PROGRAM BUDGET	\$ 85,457

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

SCHEDULE 10

CLINICA MONSENOR OSCAR A. ROMERO

ROUTINE HIV TESTING IN CLINICAL SETTINGS USING THE ORAQUICK RAPID HIV-ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

	<u>Budget Period</u>
	January 1, 2005 through <u>September 14, 2005</u>
Salaries	\$ 97,255
Employee Benefits	\$ 26,259
Total Salaries and Employee Benefits	\$ 123,514
Operating Expenses	\$ 6,562
Capital Expenditures	\$ -0-
Other Costs	\$ -0-
Indirect Costs	\$ 12,351
TOTAL PROGRAM BUDGET	\$ 142,427

During the term of this Agreement, any variation to the above budget must have prior written approval of the Office of AIDS Programs and Policy's Director. Funds shall only be utilized for eligible program expenses.

EXHIBIT E-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV using the OraQuick Rapid HIV-1 Antibody Test as part of a Routine Medical Screening to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

3.0			2.0			1.0	
By 12/31/04, 100% of clients completing a Rapid Test will receive disclosure services.			By 12/31/04; a minimum of 372 (85%) patients who accept services will receive Rapid HIV testing.			By 12/31/04, a minimum of 438 patients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S)
3.1	2.3	2.2	2.1	1.3	1.2	E	
Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer rapid HIV test. Document test results on PDA. Submit findings to OAPP.	Administer consent form, medical release form, and disclaimer. Complete client logs.	Develop consent forms, medical release forms, disclaimers and client logs. Submit materials to OAPP for approval.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Develop Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	IMPLEMENTATION ACTIVITIES
5/18/04 and ongoing	5/18/04 and ongoing	By 6/18/04	5/18/04 and ongoing	5/18/04 and ongoing	5/18/04 and ongoing	By 6/18/04	TIMELINE
3.1	2.3	22	2.1	1.3	1.2	Ľ	0
Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Calendar will be kept on file and submitted with monthly reports to OAPP	Letter(s) of OAPP approval and related material will be kept on file.	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

EXHIBIT E-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV using the OraQuick Rapid HIV-1 Antibody Test as part of a Routine Medical Screening to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angdes

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3.0			2.0			1.0	
By 12/31/05, 100% of clients completing a Rapid Test will receive disclosure services.			By 12/31/05, a minimum of 637 (85%) patients who accept services will receive Rapid HIV testing.			By 12/31/05, a minimum of 750 patients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S)
3.1	2.3	2.2	2.1	1.3	1.2	E	
Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer rapid HIV test. Document test results on PDA. Submit findings to OAPP.	Administer consent form, medical release form, and disclaimer. Complete client logs.	Review and revise, as needed, consent forms, medical release forms, disclaimers and client logs. Submit materials to OAPP for approval.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Review and revise, as needed, Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	IMPLEMENTATION ACTIVITIES
1/1/05 and ongoing	2/1/05 and ongoing	By 2/01/05	1/1/05 and ongoing	1/1/05 and ongoing	1/1/05 and ongoing	By 2/1/05	TIMELINE
3.1	2.3	22	2.1	Ĺ	1.2	E E	_
Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Calendar will be kept on file and submitted with monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) PREVENTION SERVICE FOR HIV INFECTED PERSONS SERVICES AGREEMENT

Amendment No. 3

	THIS AMENDMENT is	s made and entered into this day
of _		, 2004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	THE LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER, D.B.A THE LOS ANGELES GAY AND LESBIAN CENTER (bereafter "Contractor")

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) PREVENTION SERVICE FOR HIV INFECTED PERSONS SERVICES AGREEMENT", dated November 14, 2000, and further identified as Agreement No. H-211828, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend and amend Agreement to provide changes set forth herein; and

WHEREAS, as a recipient of State and/or Centers for Disease Control funds, Contractor will participate in the Los Angeles County Eligible Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of State and/or federal Centers for Disease Control and Prevention (CDC) funds, where there is a Service Provider Network (SPN) in the SPA in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must implement a "consumer advisory committee" with

regular meetings and consumer membership as a mechanism for

continuously assessing client need and adequacy of

Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor must actively collaborate and recruit referrals

from service organizations and agencies beyond the Ryan White

CARE Act service delivery system, including, but not limited

to, substance abuse, mental health, primary health care and

social services organizations.

WHEREAS, as a recipient of State and/or CDC funds,

Contractor's referrals to and from organizations must be noted

and tracked in the OAPP service utilization data system, and

followed up in client need and adequacy of Contractor's

services, and to obtain client feedback.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties hereto agree as follows:

- This Amendment shall be effective the date of Board Agreement.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on November 14, 2000 and continue in full force and effect through December 31, 2004. Said Agreement shall thereafter be renewed for a nine (9) month and two (2) week term effective January 1, 2005 through September 14, 2005 subject to the availability of Federal, State or County funds. If such funding is not forthcoming, this agreement shall terminate on December 31, 2004. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. In any event, County may terminate this Agreement in accordance with the TERMINATION Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, A-1, D, D-1, D-2 E, E-1, F, F-1 and F-2, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>,
 Subparagraphs E and F, shall be added to Agreement as follows:
 - "E. During the period date of Board approval through December 31, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Ninety-Nine Thousand, Four Hundred Eighty-Seven Dollars (\$99,487). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 11, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Partner Counseling and Referral with HIV Testing Services.
 - F. During the period January 1, 2005 through
 September 14, 2005, the maximum obligation of County for
 all services provided hereunder shall not exceed One
 Hundred Sixty-Five Thousand, Eight Hundred Thirteen

Dollars (\$165,813). Such maximum obligation is comprised entirely of CDC funds. This sum represents the total maximum obligation of County as shown in Schedule 12, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Advancing HIV Prevention Initiative, Partner Counseling and Referral with HIV Testing Services."

- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. <u>COMPENSATION</u>: County agrees to compensate

 Contractor for performing services hereunder for actual

 reimbursable net cost basis as set forth in Schedules 1,

 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12, and the <u>COST</u>

 <u>REIMBURSEMENT</u> Paragraph of the body of this Agreement."
- 6. Paragraph 16, <u>HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996</u> shall be added to Agreement as follows:
 - "16. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

 ACT OF 1996: The parties acknowledge the existence of the

 Health Insurance Portability and Accountability Act of

 1996 and its implementing regulations ("HIPAA").

 Contractor understands and agrees that as a provider of

 medical treatment services, it is a "covered entity" under

agree to take all necessary and reasonable actions to comply with the requirements of the HIPAA law and implementing regulations related to transactions and code set, privacy, and security. Each party further agrees to indemnify and hold harmless the other party (including their officers, employees, and agents), for its failure to comply with HIPAA."

- 7. Exhibits F, F-1, and F-2, SCOPES OF WORK FOR HIV/AIDS PREVENTION FOR HIV INFECTED PERSONS PARTNER COUNSELING AND REFERRAL WITH HIV TESTING SERVICES, are attached hereto and incorporated herein by reference.
- 8. Schedules 11 and 12, BUDGETS FOR HIV/AIDS PREVENTION
 FOR HIV INFECTED PERSONS PARTNER COUNSELING AND REFERRAL
 WITH HIV TESTING SERVICES, are attached hereto and
 incorporated herein by reference.
- 9. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

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Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

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APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

DEPARTMENT OF HEALTH SERVICES

APPROVED AS TO CONTRACT ADMINISTRATION:

By ______ Irene E. Riley, Director Contract Administration

EXHIBIT F

THE LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER, d.b.a. THE LOS ANGELES GAY AND LESBIAN CENTER

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES AGREEMENT

1. DEFINITION: Partner counseling and referral services (PCRS) with HIV testing using the OraQuick Rapid HIV-1 antibody test services provide PCRS to HIV-positive individuals; HIV testing services to identified sex or injection drug use partners; pre- and post-test counseling for HIV antibodies; referrals to appropriate health and social services as needed by client; and the provision of appropriate HIV risk reduction intervention based on client's need. services shall be provided through clinics, health facilities, or non-clinic based community services providers. For the purposes of this Agreement, a linked referral is any referral that is facilitated by the providers and confirmed as met by the referring agency. At a minimum, a linked referral must include: referral information provided in writing and verification regarding client's access to services. Routine HIV testing using the OraQuick Rapid HIV-1 antibody test services are provided free of charge and on confidential basis.

provisions set forth in the COST REIMBURSEMENT Paragraph of this Agreement.

5. <u>SERVICE DELIVERY SITE(S)</u>: Contractor's facilities where services are to be provided hereunder are located at:

1625 North Schrader Boulevard, Los Angeles, California 90028;

1125 North McCadden Place, Los Angeles, California 90038; and other sites as approved by OAPP's Director.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before terminating services at such location(s) and/or before commencing such services at any other location(s). OAPP reserves the right to approve and deny all requests and will make such decisions based on the appropriateness of the request.

6. SERVICES TO BE PROVIDED: During each term of this Agreement, Contractor shall provide PCRS with HIV testing using the OraQuick Rapid HIV-1 antibody test to persons meeting the eligibility criteria, in accordance with procedures formulated and adopted by Contractor's staff, the Centers for Disease Control and Prevention (CDC); consistent with California law; California Department of Health Services (CDHS) - Office of AIDS (OA) guidelines and the terms of this Agreement. The Director of OAPP shall notify Contractor of any revisions to OAPP policies and procedures, which shall

become part of this Agreement. Pre-test and disclosure counseling shall follow Los Angeles County guidelines for HIV Prevention Counseling as adopted by the Centers for Disease Control and Prevention (CDC) and CDHS-OA. All counseling sessions shall take place in a private, face-to-face session in closed room or area that ensures patient confidentiality. All PCRS shall follow the CDC guidance on HIV PCRS. Additionally, Contractor shall provide such services as described in Exhibits F, F-1 and F-2, Scopes of Work, attached hereto and incorporated herein by reference.

Minimum services to be provided shall include, but not be limited to, the following:

- A. Provide PCRS to at least 80% of newly diagnosed HIV-positive persons upon acceptance by client.

 Individuals who do not wish to receive PCRS will be asked for their age, gender, race and reasons for refusal so that characteristics of non-respondents can be evaluated.
- B. Provide Confidential testing upon acceptance by client. Individuals who do not wish to receive counseling and testing will be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. For those clients who wish to only be tested

anonymously, a referral to an anonymous HCT site will be provided.

C. Provide a client-centered counseling session that engages the client in a dialogue that encourages the disclosure of unique individual needs and concerns related to HIV risk and emphasizes personal options that limit or prevent transmission of HIV. During the session the counselor should also explain the differences and methods of standard testing (serum and/or oral fluid) and OraQuick testing, the procedures related to each of the testing options, and any relevant information regarding the "window period." Additionally, the client-centered counseling session should accomplish the following: improve the client's self-perception of risk; b) support behavior change previously accomplished or attempted by the client; c) negotiate a workable short-term and longterm risk reduction plan based on the client's perceived ability to change his or her behavior; d) support informed decision-making about whether to be tested; e) obtain informed consent; f) obtain consent to draw a confirmatory test specimen in the event the rapid test result is preliminary positive; g) review the nexus between HIV and STD infections; h) ensure that the client understands the meaning of test results, including a reactive OraQuick result requiring confirmatory testing; and i) assess the client's potential reaction to receiving a reactive rapid test. The Contractor shall fully collect client demographic information using the handheld computer system using iPAQ Pocket Personal Computers provided by OAPP. All information reported on the approved device(s) and lab slips shall be voluntarily supplied by the client.

7. Provide an FDA-approved Rapid HIV-1 antibody test to determine the presence of HIV antibodies. The provision of screening procedures shall be preceded by a review with the client of the following areas: a) information regarding risks and benefits of the Rapid HIV-1 antibody test; b) an explanation of the meaning of the respective test results; c) an explanation of the respective testing procedures; d) information on the importance of a confirmatory test if the test result is preliminary positive; e) a review of the HIV-antibody window period; and f) completion of OAPP-approved consent form signed by the client and maintained in the client's file in accordance with the California Code of Regulations.

- A. The HIV Certified Counselor shall ensure to follow the steps to testing using the OraQuick Rapid HIV-1 Antibody test as delineated in the OraQuick package insert and in the Step-by-Step Instructions for OraQuick Rapid HIV-1 Antibody Test.
- B. Conduct a client-centered disclosure counseling session that serves to provide the client with their results and that integrates the test result in a meaningful and productive manner based on their reported risk factors and consistent with their risk reduction efforts. Test results shall not be mailed, nor disclosed over the phone, nor given to anyone except the client, nor given in the presence of other persons with the exceptions stipulated by California Health and Safety Codes 121010, 121015, 121020, 120975, 120980, and 120985.
- C. The HIV Certified Counselor reviewing the client's Counseling Information shall precede the disclosure session. The HIV Certified Counselor personalizing and framing the session to the client to establish a comfortable setting by describing disclosure session steps shall precede the disclosure event. The HIV Certified Counselor shall disclose the results, review the medical interpretation of the test result and

assess the client's emotional state, counseling needs, understanding of the test results, need to be re-tested based on the window period and recent risk behaviors, and need for a confirmatory test for preliminary positive results. The HIV Certified Counselor shall assess the client's understanding of and commitment to risk reduction guidelines as well as the strength of social support and plans for and consequences of disclosure to others.

D. For clients testing HIV-positive, the following additional topics shall be covered in the disclosure session; a) information regarding the confirmatory test when test results are preliminary positive; b) information regarding the risk of HIV transmission to the fetus or newborn during pregnancy, during labor and delivery, and during the postpartum period if the individual is a woman or the male partner of a women of childbearing age; c) information on the risks of reinfection; e) written documentation of information and/or assistance with partner notification and/or linkage to Los Angeles County Department of Health Services Partner Counseling Referral Services (PCRS) and field follow-up services for assisted partner notification; and e) a

written assessment of the client's reaction to the positive test result to determine whether referral for psychosocial support services, including suicide prevention, is indicated.

The HIV Certified Counselor shall assess the need for referrals and provide specific, written referrals with adequate linkages as appropriate. At a minimum, referrals to the following services shall be considered based on client risk and test results: risk reduction, prevention for HIV-infected persons, mental health counseling, partner counseling and referral services, and tuberculosis screening and drug treatment services. For HIV-positive clients written referrals to a minimum of three (3) primary medical care providers shall be provided and any other linked referrals appropriate to the immediate health and social needs of the client. The Contractor shall document all linked referrals and referral follow-up for each person served under this Agreement. The linked referral follow-up shall include, but not be limited to, the agency the person was referred to, any appointment(s) made, no show for said appointment, and follow-up plan, if the individual failed to show for confidential testing.

- F. Contractor shall comply with the Interim
 Revision of Requirements for Content of AIDS-related
 Written Materials, Pictorials, Audiovisuals,
 Questionnaires, Survey Instruments, and Educational
 Sessions in Centers for Disease Control Assistance
 Programs, as referenced in Exhibit B.
- G. Contractor shall obtain written approval from OAPP's Director for all educational materials utilized in association with this Agreement prior to its implementation.
- H. Contractor shall submit for approval such educational materials to OAPP at least thirty (30) days prior to the projected date of implementation. For the purposes of this Agreement, educational materials may include, but not limited to, written materials (e.g., curricula, pamphlets, brochures, fliers), audiovisual materials (e.g., films, videotapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings).
- I. Failure of Contractor to abide by this requirement may result in the suspension of this Agreement at the Director's sole discretion.

HIV counseling and testing is being made available as part of PCRS services. DIS shall explain the following: (1) the HIV testing process; (2) the use of an OraQuick® rapid HIV test; (3) only confidential testing is being offered (referrals will be provided to other clinics offering anonymous HIV testing); (4) the difference between a standard blood test, an oral (OMT) test, and the rapid test; (5) the type and method of specimen collection; (6) the waiting time for results; (7) what different results mean; (8) and confirmatory testing. Upon brief discussion of these topics, the DIS shall confirm the individual's willingness to discuss HIV rapid testing. Upon consent (both verbal and written), the counselor shall engage the client through the standard pre-test counseling and informed consent process.

(2) Individuals Refusing HIV Counseling and Testing: Individuals who do not wish to receive counseling and testing shall be asked for their age, gender and race so that characteristics of non-respondents can be evaluated. Some individuals may not wish to discuss HIV counseling and testing

because they are already HIV positive. In these cases, DIS shall determine if the individual is receiving medical care for his/her HIV infection, as well as providing referrals for services, including additional medical care services, and other community and psychosocial services. If a need for such services is identified, the individual shall be referred to the appropriate service provider.

Referrals for medical care, social services (not limited to housing, transportation, community support, education), and mental health shall be made available to all clients regardless of their decision to test.

- (3) Individuals Accepting HIV Counseling and Testing: Demographic information shall be collected (i.e., gender, age, and race). If the potential client is found to be ineligible, the reason for ineligibility shall be recorded (e.g., underage, mental instability, etc).
- (4) Pre-test Counseling and Informed Consent:
 Individuals who meet the established eligibility
 criteria as described above, and consent to test,
 shall be escorted to a room or space in which

counseling and testing using the OraQuick® HIV rapid test and counseling can be performed in private. The OraQuick® HIV rapid test shall be provided to clients free of charge. Only confidential tests shall be performed so that follow-up for provision of medical and psychosocial services may be accomplished. Clients who wish to test via an anonymous test shall be directed to other testing facilities where an anonymous test may be obtained. Clients agreeing to a confidential HIV rapid test shall identify a private setting in their home (or the DIS shall identify a private place in other field settings) where the HIV counseling and testing may be performed. The room or space shall be well lit (to adequately read rapid test results) and must have a workspace with a level surface or DIS must provide a level surface (to ensure that the test kit tray is at the proper angle), and must be within acceptable temperature parameters (59° - 80°F) for performing the OraQuick® test. Staff shall explain the following: the differences and methods of standard testing (serum and/or oral fluid) and OraQuick® testing; procedures related to each of the testing options-how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat testing; and relevant information regarding the "window period" i.e., the time between possible exposure to the HIV virus and when the test is likely to identify HIV antibody in the patient specimen. If the client decides to be tested with OraQuick®, staff shall: ensure that the client understands the meaning of test results, including that a reactive OraQuick® result requires confirmatory testing; assess client's potential reaction to receiving a reactive rapid test. Some clients may realize that they are not prepared to receive their result today and elect to have a standard test; other clients may indicate the intent to harm themselves or others based upon receiving same-day results. In these situations, testing shall be deferred and The DIS shall follow local protocols related to ensuring staff and client safety. Clients who are prepared to undergo the rapid HIV test must provide informed consent for confidential HIV testing according to local standards. The informed consent process shall also

reflect the necessity of collection a blood specimen via venipuncture for individuals testing preliminary positive via OraQuick®. (HIPPA consent forms are attached).

- (5) Performing the OraQuick® Rapid HIV-1 Antibody Test:
 - (a) Materials Required for Testing: The following materials are provided to the site:

 (1) the OraQuick® Rapid HIV-1 Antibody Test packaged in a divided pouch that contains the device; (2) reusable test stands; (3) specimen collection loops; (4) subject information pamphlets; (5) package insert; and (6) external controls (set of positive and negative).
- M. The following materials are not provided to the site but are required. Agencies must have all of these materials prior to testing: (1) latex, vinyl or nitrile disposable gloves; (2) sterile retractable lancets; (3) timer or watch capable of timing 20-60 minutes; (4) clean, disposable, absorbent workspace cover; antiseptic wipes; (5) sterile gauze pads (2"x2"); (6) small adhesive bandages; (7) biohazard sharps container and trash bags; (8) surface disinfectant (EPA-registered, hospital grade,

intermediate activity disinfectant such as Dispatch,

Virex TB, or Cavicide); (9) alcohol-based waterless hand

cleanser; (10) laboratory grade thermometers to measure

storage temperature of test devices and controls and

temperature of testing location; and (11) required forms.

- N. <u>Conditions for Testing</u>: The following conditions must be present to use OraQuick®: (1) sufficient lighting to safely and accurately perform the test and read the result; (2) a level, clean surface where testing can be performed; (3) temperature of the test kit and test area between 59° and 80° Fahrenheit; (4) space that assures confidentiality for both testing and counseling.
- O. <u>Use of External Kit Controls</u>: Sites shall be supplied with external controls that verify whether the devices are working properly or staff is properly performing the test. The positive control (the black cap) contains a serum-based solution containing antibodies that will show a reactive result when used with the OraQuick® test. The negative control (the white cap) will show a non-reactive result when tested. If the device does not show the expected result when each control is used, either the test was not performed

properly or the device is defective. Staff shall thoroughly review all of their testing procedures prior to assuming that the device is defective. External Kit Controls shall be run under the following conditions: (1) when a staff person has been trained to conduct OraQuick® testing, prior to testing client specimens; (2) when a new box of test kits is opened at the testing site; (3) when testing conditions change; if the temperature of the test kit storage area falls outside 35'-80' Fahrenheit; (4) if the temperature of the testing area falls outside 59°-80° Fahrenheit; (5) including any of the above reasons, external controls shall be conducted at least once every 25 tests or once a month - whichever occurs first; (6) the external controls must be refrigerated (temperature must be between 35'-46' Fahrenheit). Controls do not need to be warmed to room temperature prior to use. Although the controls have an expiration date that is one year post-production, once controls are opened they must be used within 3 weeks. Controls shall be dated when they are opened and discarded 3 weeks after this date. As a reminder, staff may wish to record on a refrigerator log when controls shall be disposed.

- P. Testing Steps: Staff shall complete the following steps when administering an OraQuick® test. More detailed instructions are delineated in the OraQuick® package insert and in the "Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test. Staff shall familiarize themselves with both of these resources prior to testing clients.
 - Preparation: Cover the workspace with an absorbent cover. Place stand, divided pouch, loops, antiseptic wipes, sterile retractable lancet, disposable gloves, sterile gauze, and bandages at workspace. Check expiration date of packet. expired, dispose and obtain a new pouch that is not expired. Check to make sure there is an absorbent packet in the device side of the pouch. If none is present discard the entire pouch and obtain a new one. Open the two chambers of the divided pouch and label the test device AND the developer solution vial with a pre-printed project ID number sticker (it is also helpful to write the client code or client initials on the sticker). Keep the paddle end of the device inside the package to avoid contamination. Do Not Cover the holes on the back

of the device. Remove the cap from the vial and slide it into the stand from the top. Place the cap on the absorbent cover near the stand. Put on disposable gloves.

- Standard section for detailed finger stick blood collection procedure): Clean the patient's finger with an antiseptic wipe and allow it to dry thoroughly. Using a sterile retractable lancet, puncture the skin just off the center of the finger pad. Discard lancet in a sharps container. Allow a drop of blood to form and wipe it away with sterile gauze. Allow a second drop of blood to form and place the loop onto this drop. Make sure the blood fills the inside of the loop.
- (3) Mixing: Insert the loop into the vial being careful not to touch the loop to the sides of the vial. Stir the solution with the loop to properly mix. Discard the loop in a waste container. Make sure the solution appears pink.
- (4) Testing: Remove the device from the pouch.

 DO NOT touch the Flat Pad. Insert the Flat Pad end

 of the device into the developing solution with the

result window facing forward. Note the starting time on the testing log. It also may be helpful to set a timer for 20 minutes. Read the result of the test after 20 minutes but not more than 40 minutes from the time the device was placed in the solution.

- (5)Reading the result: A valid test result must have a reddish-purple line next to the "C" (Control) triangle. If no line is present at this area, the test is invalid and no result can be interpreted. In this case, the client must be tested again. A line at only the "C" triangle, and no line at the "T" (Test) triangle, is interpreted as a non-reactive or negative test result. The client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client shall be re-tested 3 months after the exposure. Lines at both the "C" and "T" area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen from the client to determine whether the client is infected with HIV.
- (6) Assessing Invalid Results: To assess why a test may be invalid, staff shall review their

procedures to determine that the test was conducted properly. A second test shall be conducted. If this test is also invalid, external kit controls shall be run. If the expected results are not obtained, staff shall contact local laboratory staff. If it appears that devices are defective, the OraSure customer service department shall be contacted at 1-800-672-7873.

- (7) Documentation of the Result: Be certain that both the vial and the device within the vial have the same ID number and client code/initials. Staff shall record the date of the test and the Client Name or anonymous code on the agency "OraQuick® Rapid HIV Result Log form . The result, date and time, temperature, and counselor ID, and test reader shall also be recorded on the log. Place a checkmark in the appropriate area indicating whether the result was non-reactive or reactive, and the type of confirmatory test preformed. Provide the client with the written result. The agency keeps a copy of this result for its records.
- (8) Clean up: Dispose of retractable lancets in a sharps container and all other used test

materials (capped vial, device, loops, used gauze and gloves, etc.) in a trash bag. Clean any spills with a surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide). Remove gloves and wash hands after every test is performed. Use new gloves for each client.

(9) Confirmatory Testing: All clients receiving a reactive (Preliminary Positive) OraQuick® result shall be asked for consent to immediately have a specimen collected for the confirmatory Western blot test to determine whether they have HIV infection. All clients consenting to test, shall be asked for an additional confirmatory specimen, in the event that their rapid test is preliminary positive. A serum or oral fluid specimen shall be obtained from the client and sent to a laboratory for Western blot testing (the specimen shall be sent to either the LAC Department of Health Public Health Laboratory, or a number of private laboratories throughout Los Angeles). type of specimen collected for confirmatory testing (i.e., serum or oral fluid) will depend upon the

type and availability of the client-requested testing methodology, and that particular project site's available testing resources.

- Q. <u>Post-test Counseling and Referral</u>: Post-test counseling consists of providing the results (disclosure) to the client and arranging for any follow-up testing, services, or referrals.
 - (1) Disclosure of Preliminary Positive (Reactive) Results: The following information shall be covered when providing post-test counseling to a client with a reactive OraQuick® result. Throughout this process, counselors shall provide emotional support to assist the client to cope while waiting for the confirmatory test. In addition, each site shall call upon their designated case manager, or social worker to assist in the provision of positive results. In the event that a client requests additional services or appointment with the client advocates, and the requested staff is not available, provisions shall be made to schedule an appointment with the client advocate for a later day. Consent may also be obtained so that the client advocate may contact the client to schedule an appointment.

R. <u>Disclosure of Confirmed Positive Results</u>:

During the disclosure of a preliminary positive

(reactive) results, the test counselor shall: interpret

the result and assess client understanding of the result;

explain confirmatory testing; obtain commitment from

client to return for confirmatory result; discuss what

client intends to do during waiting time, including

disclosure issues; encourage client to take precautions

to avoid potentially transmitting the virus to others;

and assess need for referrals.

- (1) Interpret the result and assess client understanding of the result: Reactive results are defined as "preliminary positives" by the Centers for Disease Control and Prevention (CDC). However, this term may be confusing since all clients may not understand the word "preliminary" and "positive" has intense associations with it. By hearing the word "positive" clients may believe they are infected with HIV, regardless of how the counselor describes this screening result.
- (2) Explain confirmatory testing: A specimen for confirmatory testing shall be obtained immediately for Western blot testing. If possible,

a blood specimen shall be drawn. If the counselor does not perform phlebotomy, an oral fluid specimen can be obtained. Counselors shall tell clients that if the confirmatory test result were negative, a second confirmatory test - a serum test - would be done to be absolutely certain that they are not infected.

- (3) Obtain commitment from client to return for confirmatory result: Counselors shall set an appointment with the client to receive the confirmatory test result. The appointment time shall be set in accordance with the amount of time necessary for confirmatory test results to be received from the local laboratory.
- (4) Discuss what client intends to do during waiting time, including disclosure issues.

 Counselors shall discuss how clients intend to cope during this waiting period and who if anyone they intend to tell about their rapid test result.

 As with someone who has just received a confirmed positive result, counselors shall examine with the client who they will trust with the result, and the potential ramifications of disclosing their result

- widely. If their confirmatory result is negative, the client may also have to contend with contacts mistakenly believing that he/she is HIV infected.
- (5) Encourage client to take precautions to avoid potentially transmitting the virus to others:

 Counselors shall encourage and support the client in use of risk reduction behaviors to avoid potentially transmitting the virus to others. This includes examining the client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.
- need emotional support during this waiting period.

 Minimally, counselors shall offer to be a support to the client via phone or in person. In addition, the client may need referrals to a mental health counselor, risk reduction specialist, or crisis line. Counselors shall assess the need for referrals based on the steps defined in the Revised Guidelines for HIV Counseling, Testing and Referral. Counselors shall discuss the services that are available to them if their confirmatory test is positive. A brief description of partner counseling

and referral services, as well as access to medical care, legal services, case management, and the drug reimbursement or health insurance programs shall be provided.

S. <u>Disclosure of Non-reactive results</u>: following information shall be covered when providing post-test counseling to someone with a non-reactive OraQuick® result. Interpret the result and discuss possible need for re-testing: A non-reactive OraQuick® result is interpreted the same as for standard HIV antibody testing. The result is interpreted as negative unless the client has engaged in risk behavior within the last three months. If the client has engaged in risk behavior during this time, counselors shall recommend a re-test three months after their last exposure. In rare cases, individuals have been known to seroconvert as late as six months after an exposure. If the client has had an exposure to someone who is known to be HIV positive, it may be advisable to recommend a re-test at six months after this exposure. Assess need for referrals: Counselors shall assess for additional services needed by the client, such as STD or hepatitis testing, alcohol and other drug abuse treatment, economic assistance, domestic violence services, housing, etc.

- Τ. <u>Disclosure of Confirmed Positive Results</u>: The following information shall be covered when providing post-test counseling to someone with a confirmed positive HIV test result. Throughout this process, counselors shall provide emotional support to assist the client to cope with their HIV+ diagnosis. In addition, each site shall call upon their designated case manager or social worker to assist in the provision of positive results. Client advocates shall offer post-disclosure services that may include emotional and community support, information/assistance regarding identification and entry into medical care, PCRS services, medical and community referrals, and follow up. In the event that a test counselor needs additional support with a client, provisions shall be made to schedule an appointment with the client advocate for a later day. Consent may also be obtained so that the client advocate may contact the client to schedule an appointment.
- U. Result of the Confirmatory HIV Test: Sites shall follow local protocols for reporting Western Blot HIV positive results to local and CDC surveillance.

- (1) Western Blot Confirmed HIV-Positive Test Result: When the DIS receives the Western Blot confirmatory HIV-positive result, they shall check the state/local HIV/AIDS reporting system to determine whether the client has been previously reported to the surveillance system. Clients that have previously tested positive for HIV are still eligible for services from the Client Advocate, but will not need to be reported to the local surveillance system. The process for providing results begins with the client's appointment for results. If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the test result protocol listed below.
- (2) When the client keeps their appointment for confirmatory test results, the Client Advocate shall provide confirmatory test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. In addition, the Client Advocate shall refer the client to medical services and

reassess the client for psychosocial services. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment. If the client does not make their appointment for referrals services, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the steps outlined in the Monitoring Care services section below.

V. Monitoring Care: After the client has been linked to medical and psychosocial services, the Client Advocate shall determine whether or not the client was successful in obtaining medical care. All project staff shall be trained on using the OAPP HIV/AIDS Information Resources System (HIRS) system to both obtain consent for and the enrollment of recently diagnosed clients into HIRS. OAPP staff shall take the lead in reviewing HIRS and IMACS/Casewatch data for follow up of consenting demonstration project clients. Review of their information will provide CDC with follow up information such as T-cell counts and viral load. This review process shall begin approximately three to six months

after the client's appointment for confirmatory results to allow sufficient time for the client to enter care and for the lab reports to be entered into the surveillance system. Periodic review of the HIV/AIDS Reporting System shall occur until a T-cell and/or viral load is recorded. The Client Advocate (in this case, the Client Advocate is the case manager that is assigned to the client when they enroll in medical care services) shall ensure that all medical appointments are kept, and shall continuously offer services including PCRS. IMACS/Casewatch will provide client level reports that assess whether appointments were missed and the Client Advocate shall address missed appointments. This information shall be included with the regular data reports that are sent to CDC.

W. Western Blot HIV-Negative Test Result: If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate (in this case, the HIV counselor/project staff) shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the HIV counselor/project staff shall follow the test result protocol listed below. When the client keeps their appointment for confirmatory

test results, the Client Advocate (in this case, the HIV counselor/project staff) shall provide negative test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the Client Advocate shall instruct the patient to return for testing in one month, due to the discordant results between the OraQuick rapid HIV test and the Western Blot. When available, the confirmatory (Western Blot) test shall be done with a standard serum HIV test. If blood testing is not available, or in the absence of trained clinical staff (phlebotomist), an oral fluid test shall be used. In addition, the Client Advocate shall reassess the need for psychosocial services. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

X. Western Blot Indeterminate Result: If the client does not make their appointment to obtain results of the confirmatory test, the Client Advocate shall follow the Lost to Follow Up Protocol. If the client is located after following this protocol, the Client Advocate shall follow the test result protocol listed below. When the client keeps their appointment for

confirmatory test results, the Client Advocate shall provide indeterminate test results according to the CDC Revised Guidelines for HIV Counseling, Testing and Referral. At this time the DIS shall recommend that the partner seek additional HIV testing in one month, due to discordant results due to the discordant results between the OraQuick rapid HIV test and the Western Blot. The second Western Blot test shall be a standard serum HIV test, not an oral fluid test. In addition, the Client Advocate shall reassess the need for psychosocial services. The Client Advocates shall contact the appropriate referral service provider(s) and schedule an appointment for the client. The Client Advocate shall then contact the referral service provider(s) to ensure that the client followed through with the appointment.

Y. <u>Linkage to Care</u>: LA County OAPP HIV/AIDS
Information Resources System (HIRS. The HIV/AIDS
Information Resources System (HIRS) is an integrated,
browser-based application system designed to meet the
business systems needs of LAC Office of AIDS Programs and
Policy (OAPP) and its provider agencies. Upon disclosure
of (confirmed) positive results, the HIV counselor/PCRS
project staff registers the client into the HIRS system.

The HIRS is linked to the IMACS/Caswatch system (the care services data system), which collects client demographic and diagnostic information for those clients enrolled in LA County's network of Ryan White CARE providers. is designed to ensure that the post-test return rate for persons testing HIV-positive is maximized, that all persons testing HIV-positive are effectively linked into care, and that mandated eligibility screening for people seeking CARE Act-funded services has effected the maximum use of alternate payer sources (such as MediCal, Medicaid, private insurance and VA benefits). Once the client advocate has identified referral needs after the client has received the rapid HIV test results, the client advocate must provide a link to the referral sources for the client. If the client refuses psychosocial needs assessments, the client advocate shall provide the client with information regarding appropriate resources and contact information for each referral source. In addition, the client advocate shall schedule a confirmatory HIV test result appointment for the client. Client Advocates shall contact the appropriate referral service provider(s) and schedule an appointment for the client. The Client Advocate shall then contact

the referral service provider(s) to ensure that the client followed through with the appointment. For HIV negative clients, resources and referrals to support groups, social and mental health services and information about community-based organizations shall be provided. For high-risk negative clients, these services may include additional risk reduction education and community and social support services, as well as testing for other STDs. The client shall also have the opportunity to schedule a post-disclosure session with the liaison, to follow up on referrals, additional testing, or the development of a risk reduction plan. For HIV Positive clients, the PCRS Liaison is able to provide immediate access to in-house medical care, case management and social support systems during normal operating hours. For clients identified during non-operating clinic hours. In the event that a positive test occurs after operating hours, a call shall be placed to a case manager that evening with information that the client may be showing up first thing in the morning. The client shall be given a documented referral for medical care. In the event that a client tests positive at night, and the client has no one to talk with, or is not emotionally able to be

left alone, a social worker shall be called in, regardless of time. After assessing the client's willingness to discuss treatment, the clients shall be referred to in-house clinicians who can begin the medical assessment and treatment enrollment for HIV-positive clients. Referrals shall be given to for other medical and treatment providers, in the event that a client wishes to receive care elsewhere. Client Advocates (PCRS liaisons, case managers, social workers medical and mental health clinicians) shall work with the client to provide referrals that are tailored to the client's geographic, language and culture preferences. In-house client case managers or social workers shall be available to provide additional services to the client. These services include facilitation, referral and enrollment into medical care. In addition, the client advocate shall be prepared to offer other referrals for substance abuse treatment, mental health, PCRS services, and follow up.

Z. <u>Data Collection Procedures</u>: Computer systems

(Pocket PCs) - Client-level data collected for this

project shall be sent directly to the OAPP Data and

Epidemiology Unit. OAPP staff shall collect, manage,

review, analyze and disseminate this data to CDC based on their proposed schedule of reporting. HIRS data collection/management is described in the HIRS section of the protocol. Client Tracking - Printed labels containing client IDs (in sets of 8) shall be provided to PCRS staff to facilitate the tracking of client records. Labels shall be applied to each of the following documents (described later) and to specimens collected for confirmatory testing: the Initial Encounter Form/Card; the HIV Rapid Testing Demonstration Projects Questionnaire for paper versions (client ID entered into Pocket PCs for electronic version); the Test Results Log; the Client Advocate Log; OraQuick® Rapid HIV Test; and Confirmatory HIV test specimen. Initial Encounter Card: These palm-sized cards shall be utilized by PCRS staff as a record of the completed counseling and testing session. The pre-printed client ID number sticker shall be affixed to this card and passed on to the Client Advocate. will ensure that both the DIS and the Client Advocate have matching client ID number for the same client. All data shall be submitted to OAPP's Data and Epidemiology Unit for processing, management and analysis. Rapid Testing Demonstration Projects Questionnaire, to be

administered using Pocket PCs, contains all data elements that shall be gathered on persons who are tested for the project. Specific types of data included in the questionnaire are to follow. Data collected during the initial encounter - Utilizing the Initial Encounter Card, DIS shall attempt to collect the gender, age, and race/ethnicity of all persons approached for rapid HIV testing, regardless of willingness to participate. For persons refusing testing, DIS shall attempt to collect reasons for refusal. This data will enable investigators 1) Make comparisons between those who consented to testing with those who did not, evaluating any potential bias; and 2) Examine reasons why individuals may refuse rapid testing when offered in non-clinical settings. All initial encounter data shall be entered in Pocket PCs by the DIS. Data collected prior to rapid test - Informed consent: DIS shall, when applicable, collect reasons for a person's inability to provide informed consent. Demographic information: Site staff shall collect basic demographic information (date of birth, education status, marital status, health insurance coverage) on all persons from whom informed consent is obtained. Reasons for testing and previous testing history: DIS shall collect

information on individuals' reasons for testing, their previous testing history, and any missed opportunities for testing. Information required for Test Results Log (described later): All sites conducting rapid testing with OraQuickO shall be required to maintain quality assurance logs (see Quality Assurance Logs section, below). Prior to initiating the test, the counselor shall ensure that the client ID label has been applied to the Test Result Log, and that all other necessary information is recorded. Data collected while rapid test processes (20-40 minutes). In the event that demographic information and/or testing history data were not gathered prior to the administration of the rapid test, these data may be collected while the test is processing. HIV risk behavior: The DIS shall elicit information on client risk behavior utilizing the client-centered approach, as recommended by the Revised Guidelines for HIV Counseling, Testing and Referral. Following this discussion, the DIS shall administer specific HIV risk behavior questions from the questionnaire, recording responses into the Pocket PC. Collecting information on HIV risk in this manner ensures that project data is gathered in a standardized fashion

while still adhering to current CTR guidelines. Data collected at post-test or beyond - HIV rapid test information: DIS or Client Advocates shall record rapid HIV test results into the handheld computer. In the event that an individual does not receive rapid HIV test results, site staff shall also record the reason for not receiving results. Confirmatory testing data: For persons with a preliminary positive result, DIS or Client Advocates shall be required to enter confirmatory testing information into Pocket PCs (for the Questionnaire), the Test Results Log, and the Client Advocate Log (described later). To track the receipt of confirmatory test results, the Client Advocate shall gather client contact information and shall document the number and type of contact attempts to provide test results.

AA. Linkage to care: For all persons who are identified as HIV-positive, the Client Advocate shall track medical and psychosocial referrals and follow-through and shall monitor local HIV/AIDS surveillance data, recording specific values for the initial CD4 counts and viral loads of persons who are successfully linked into care. These data will serve as indicators of linkage to care for persons who are

confirmed as HIV positive. Client Advocate Log: Client Advocates shall be responsible for maintaining a log that includes the Client ID, name, and contact information for persons requiring follow-up (i.e., to track confirmatory testing results, receipt of confirmatory testing results, kept/missed appointments for medical and psychosocial referrals), as well as any notes necessary for tracking purposes. Identifying information collected for the Client Advocate log shall not be reported to CDC. log shall be kept in a locked, secure location when not being utilized by staff. Quality Assurance Logs: testing site shall maintain logs for quality assurance, such as those included in the appendices of the Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV Antibody Test. This information shall not be reported to CDC. Specific logs to be maintained include: Temperature Log. Site staff shall be required to record the temperature of the storage location for OraQuick test kits on a daily basis. The acceptable range for test kit storage is 2° to 27° C (35° to 80° F). For control kit storage the acceptable range is 2° to 80C (35° to 46° F), and for the testing area is 15° to 27° C (59° to 80° F). Sites shall also be responsible for periodically (e.g.,

every six months) checking and documenting thermometer performance in test kit storage areas. Control Results Test sites shall be required to document information regarding controls that are run, including the test kit lot number and expiration date, the control kit lot number and expiration date, and control test Test Results Log. Test sites shall be required to document the following information into the test results log for each rapid HIV test that is performed: test kit lot number and expiration date; test incubation time; test result and the time at which it is reported to client; and initials of the person performing the test. For each preliminary positive test result, site staff shall also record information on confirmatory testing, including: specimen tracking number; specimen type (i.e., blood, oral fluid); and confirmatory test result and the date that it is received by the client.

AB. Monitoring and Data Collection: LA County
OAPP's Data and Epidemiology unit facilitates the
collection of data for all HCT services throughout Los
Angeles County, and shall manage the data for this
project. All participating project sites shall submit
the client level data (PDA data) to the Data and

Epidemiology Unit for management, centralization and dissemination. The Data and Epidemiology unit shall submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP shall conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites shall be incorporated into the existing monitoring schedule for all OAPP contracted programs.

9. Contractor shall utilize a handheld computer system for the collection and entry of data elements gathered for monitoring and evaluation purposes. Data shall be collected using the iPAQ Pocket PCs (Hewlett-Packard) via QDS software (Nova Research). In the event that the computer malfunctions, staff may need to_utilize paper and pencil assessments as an alternative for conducting evaluation activities. Contractor shall be responsible for maintenance of their computer hardware.

- A. Contractor shall provide their own computer supplies required by the data management/data reporting process. Computer supplies include: a current version of virus protection software, utilities software, software to support platform for required electronic data management, equipment maintenance contracts, insurance, diskettes and diskette mailers, toner cartridges, printer paper, and envelopes.
- B. Contractor shall be responsible for protecting the data as described in the HIV-antibody testing data collection manual, including backup and storage of current data on disk and/or tape, keyboard password protection procedures, and utilization of a current version of PC virus detection/prevention software.
 - C. Contractor may seek assistance from OAPP for software installation, training, and troubleshooting, strategies for data management, and consultation on the process/management of the questionnaire from the client to the software.
- 10. <u>CONTRACTOR'S SUBCONTRACT/CONSULTANT REQUIREMENTS</u>:

 Contractor shall fully comply with the Subcontracting

 Paragraph of the ADDITIONAL PROVISIONS section of this

 Agreement. In addition, the Contractor shall ensure that

subcontractors and consultants providing services under this Agreement shall commence services within ninety (90) days of the execution of this Agreement, or as otherwise approved by OAPP. Subcontract and consultant agreements shall be signed and dated by the Contractor's Director, or his/her designee(s), prior to commencement of subcontracted and/or consultant services.

- 11. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit:
 - A. A monthly written report together with Data Report no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP.
 - B. Data Report for HIV/AIDS counseling, testing, immune assessment, and referral services together with monthly written report no later than thirty (30) days after the end of each calendar month. Such data shall be submitted on an appropriately labeled computer diskette generated from software designated by OAPP. Such written monthly report and computer diskette shall be mailed or delivered together to Office of AIDS Programs and Policy,

600 South Commonwealth Avenue, 6th Floor, Los Angeles, California 90005, Attention: Financial Services
Division.

C. Quality Assurance for the OraQuick® Rapid HIV-1 Antibody Test, Program Monitoring and Data Collection (procedure for all clinics). LA County OAPP's Data and Epidemiology unit provides quality assurance for all OAPP contracted counseling and testing. This includes provision of technical assistance, ordering and delivery of supplies, and ordering controls. The Data and Epidemiology unit also facilitate the collection of data for all HCT services throughout Los Angeles County, and will manage the data for this project. participating project sites will submit the client level data (PDA data) to the Data and Epidemiology Unit for management, centralization and dissemination. The Data and Epidemiology unit will submit this data to CDC as directed by their reporting and data collection schedule. In addition, LA County OAPP will conduct routine (6 month and annual) program monitoring and assessments of agencies. During these assessments, project coordinators will be asked to report on progress, staffing, budget, and will also have the opportunity to provide feedback on barriers to delivering services, and any recommendations/modifications they propose. The scopes of work and quality assurance plans for each of these project sites will be incorporated into the existing monitoring schedule for all OAPP contracted programs.

12. PROGRAM RECORDS: Contractor shall maintain and/or ensure that its subcontractor(s) maintain adequate health records which shall be current and kept in detail consistent with good medical and professional practice in accordance with the California Code of Regulations on each individual client. Such records shall include, but shall not be limited to: the dates of the HIV risk assessment session and the disclosure session, signed consent forms for confidential tests, test results, client interviews, progress notes documenting referrals provided, and a record of services provided by the various personnel in sufficient detail to permit an evaluation of services. The program records shall also include documentation of client demographic information and the statistical summary reports submitted monthly to OAPP. A current list of service providers for medical, psychosocial, and other referral resources shall be maintained.

Contractor shall maintain additional program records as follows: a) letters of OAPP approval for all materials

utilized by the program; b) documentation of staff job descriptions, resumes, and certificates and/or letters of completion of HIV Antibody Four-Day Counselor Certification Training, One-Day Re-certification Training, Three-Day PCRS certification and re-certification training, Two-Day Rapid HIV-1 Antibody Testing certification, as well as, selected STD and HIV training as attended; and c) documentation of an annual written evaluation of employee's performance and that completed evaluation has been discussed with employee. This annual evaluation shall include, but is not limited to documentation of written bi-annual observations of the counseling session, evaluation of counselor knowledge, skills and competence to provide HIV/AIDS counseling, testing and immune assessment, and referral services.

- 13. PROGRAM EVALUATION: Contractor shall assess the program's quantitative and qualitative aspects. The initial program assessment shall be conducted three (3) months following approval of this Agreement; a second assessment shall be conducted six (6) months after approval of this Agreement. The program assessments shall include:
 - A. A review of the accuracy and appropriateness of the content of the counseling sessions and the educational materials provided.

B. Observation and written evaluation of the counselors on a biannual basis. Notes on the counselor's performance and the feedback given to the counselor shall be included in his/her employee record.

Following the assessments, the Contractor shall report to OAPP on the program's progress and any problem areas following each assessment.

- 14. <u>ADDITIONAL STAFFING REQUIREMENTS</u>: The Routinely recommended HIV testing in Clinical Settings using the OraQuick Rapid HIV-1 Antibody test services shall be provided by individuals who are appropriately trained, qualified, who meet the guidelines set forth by the CDHS-OA and the CDC and are linguistically and culturally appropriate. All HIV risk assessment and disclosure counseling sessions shall be conducted by HIV Certified Counselors trained by the CDHS-OA and/or OAPP. All HIV Certified Counselors must attend an annual one-day HIV re-certification training approved by OAPP.
 - A. In addition to certification and recertification training, Contractor shall conduct ongoing appropriate staff training. All staff is required to obtain a minimum of 16 hours of continuing education units (CEU) per each term of this agreement in addition to the required re-certification training. The required

CEU training shall include, but is not limited to,

Hepatitis B and C, STDs (including chlamydia, gonorrhea

and syphilis), substance abuse and PCRS training.

- B. All testing unit staff providing direct services shall attend in-service training on substance abuse knowledge, substance misuser sensitivity, cultural approaches and substance misuse related issues, as directed by OAPP under the guidelines of the State Department of Alcohol and Drug Programs.
- C. Contractor shall document training activities in the monthly report to OAPP. For the purpose of this Agreement, training documentation shall include, but are not limited to: date, time and location of staff training; training topic(s), name of attendees and level of staff participation.
- D. All HIV Certified Counselors providing direct services shall be sensitive to the needs of persons of diverse life experiences including, substance users, persons with mental illness, transgenders, multiply-diagnosed individuals, etc.
- E. The Project Coordinator shall be appropriately trained and knowledgeable and demonstrate a high level of competency with respect to HIV/AIDS testing and

counseling issues, STD and Hepatitis C Screening, substance misuse, community referrals, and education services. The Program Coordinator shall complete the CDHS-OA and/or OAPP's HIV Counselor Certification Training and/or comparable training as approved by OAPP.

- F. Staff vacancies shall be advertised in a local newspaper and/or posted at facilities throughout Los Angeles County and/or through other methods where persons with appropriate knowledge and competency can be identified. Individuals with a history of alcohol and/or drug abuse histories who are being considered for a counselor position shall have a minimum of two (2) years sobriety.
- G. Contractor shall participate in quarterly project meetings or as directed by OAPP.
- H. Contractor shall participate in all project conference calls.
- I. Contractor shall designate one person on staff as the key person for all data collection activities related to this agreement. Said staff shall be able to represent contractor on all issues related to data collection and the evaluation thereof.

Director shall notify Contractor of any revision of these guidelines, which shall become part of this Agreement.

employment or provision of service(s) and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of a tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening." Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

approved Quality Management (QM)plan. The QM plan shall describe the process for continually assessing the contractors program effectiveness in accomplishing contractor mission, goals, and objectives. The plan shall describe the process for the following components: QM Committee, Written Policies & Procedures, Client Feedback, Program Staff, Measurable

Program/Service Quality Indicators, QM Plan Implementation, and Quality Assessment & Improvement Reports.

Quality Management Committee: The QM Committee shall develop, review, and revise the agency's QM plan on an annual basis and continually assess and make recommendations for the improvement of program services. The Committee shall be responsible for developing plans of corrective action for identified program deficiencies and consist of persons that reflect the group and/or groups to whom services are targeted including clients, volunteers, program staff, management staff, consultants, staff from other community-based organizations, etc. Program Coordinator and a client receiving services under this contract must be included as Committee members. Committee membership shall be described by name, title, or role, and the constituency represented (i.e., staff, management, and client). The Contractor shall review the Committee recommendations and ensure recommendations are appropriately implemented.

A separate Committee need not be created if the contracted program has an established an advisory committee or the like, so long as its composition and

activities conform to the criteria described in this Agreement.

The QM Committee activities shall be documented.

Required documentation shall include but not be limited to agendas, sign-in sheets, QM Committee meeting minutes (including date, time, topics discussed, recommendations, and corrective actions).

- B. Written Policies and Procedures: Policies and procedures shall be based on essential program activities and community and professional standards of care specific to this contract. The QM Plan shall describe the process for reviewing and modifying written policies and procedures. In addition, the plan shall specify the policies be reviewed at a minimum of once a year, approved and signed by the Executive Director or designee.
- C. <u>Client Feedback</u>: The QM Plan shall include a mechanism for obtaining ongoing feedback from program participants regarding program effectiveness, accessibility and client satisfaction. Describe the method(s) to be used for client feedback, (e.g., satisfaction surveys, focus groups, interviews, etc). Client feedback shall be collected on an ongoing basis or

at a minimum of quarterly. Describe how client feedback data will be managed by the QM committee and used to make improvements to the program.

- D. <u>Program Staff</u>: The QM plan shall describe the process for developing, training and monitoring staff.

 This description shall include minimum qualifications for each program staff position and a description of the methods and instruments to be used to monitor staff performance. The QM plan shall specify that staff is evaluated annually.
- E. Measurable Program/Service Quality Indicators:

 Measurable quality indicators are intended to address how well services are being provided. By developing a set of indicators specific to each program, establishing a measurable minimum standard for each indicator, and conducting an assessment on the extent to which the indicator is met, the Contractor shall assess the quality of service delivery on an ongoing basis. The QM

 Committee is responsible for developing a plan of corrective action to address any program quality deficiencies or to improve the effectiveness demonstrated by each indicator. Quality indicators shall be based on key activities described in the SERVICES TO

BE PROVIDED Paragraph of this Exhibit. The QM Plan shall require measurement of and include at a minimum the following measurable program and/or services indicators:

- (1) Process: Eighty-five (85%) test acceptance rate for clients approached for rapid testing; eighty-five percent (85%) post-test disclosure rate; one hundred percent (100%) HIV preliminary tests completing a confirmatory test; eighty percent (80%) of clients accepting referral counseling will be linked to appropriate levels of care services; follow-up services will be conducted for one hundred percent (100%) of clients testing preliminary positive.
- (2) Outcome: Eighty percent (80%) of clients receiving Rapid Testing services will report satisfaction with Rapid Testing services they received; seventy-five percent (75%) of clients receiving services will successfully demonstrate or discuss at least one risk reduction skill or plan.
- F. QM PLAN IMPLEMENTATION: Contractor shall implement its QM plan to ensure the quality of the services provided are assessed and improved on a continuous basis.

- G. Quality Assessment and Improvement Reports: The QM Plan shall include the requirement for two (2) Quality Assessment and Improvement Reports. These reports shall be developed by the QM Committee and signed by the Executive Director. Contractor shall make the following reports available to the OAPP Program Manager at the time of the monitoring review or upon request:
 - (1) Mid-Year Report shall document program performance, results of plans of corrective action, areas of concern identified by the QM Committee, and data collected from client feedback.
 - (2) Year-End Report shall document actions addressing the findings of the Mid-Year reports and the overall program performance from Mid-Year to Year-End.
- 18. EVALUATION: Contractor shall implement an evaluation plan developed by the CDC. The pan is designed to demonstrate project accomplishments and monitor areas during the course of the project in order to improve the project's success. Evaluation measure shall include, but not be limited to: (1) number of individuals approached for rapid testing; (2) number of individuals who agree to HIV testing and other types of HIV testing; (3) number of individuals who receive

rapid HIV test and confirmatory results; (4) number of HIV infected persons newly detected through rapid testing who enter into medical care; and (5) number of HIV negative persons receiving psychosocial service referrals. Contractors shall provide counseling and testing data for 2002 and 2003 for comparison purposes.

THE LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

Date of Board Approval through December 31, 2004

Budget Period

Salaries	\$ 50,398
Employee Benefits	\$ 12,302
Total Personnel and Employee Benefits	\$ 62,700
Operating Expenses	\$ 36,787
Capital Expenditures	\$ -0-
Other Costs	\$ -0-
Indirect Costs	\$ -0-
TOTAL PROGRAM BUDGET	\$ 99,487

THE LOS ANGELES GAY AND LESBIAN COMMUNITY SERVICES CENTER

PARTNER COUNSELING AND REFERRAL SERVICES WITH HIV TESTING USING THE ORAQUICK RAPID HIV-1 ANTIBODY TEST SERVICES

SERVICE PLANNING AREAS 1 THROUGH 8

	Budget Period
	January 1, 2005 through September 14, 2005
	September 14, 2005
Salaries	\$ 83,998
Employee Benefits	\$ 20,504
Total Personnel and Employee Benefits	\$104,502
Operating Expenses	\$ 61,311
Capital Expenditures	\$ -0-
Other Costs	\$ -0-
Indirect Costs	\$ -0-
TOTAL PROGRAM BUDGET	\$165,813

EXHIBIT F-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

					71
	1A.0			1.0	
	By 12/31/04,a minimum of 75% of identified partners of HIV positive clients will receive a partner notification session.			By 12/31/04, a minimum of 250 HIV positive clients will be offered Partner Counseling and Elicitation Services.	MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES
1A.2	1A.1	1.3	1.2	jumik jumik	
Conduct Partner Notification Sessions with identified partners of HIV positive clients. Document type of partner referral conducted and topics discussed during session. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	Review and revise, as needed, documentation forms for Partner Notification sessions, consent forms, clients logs. Submit to OAPP for approval.	Complete Client Log. Lob to include, but not be limited to the following; number of partners identified, number of partners who agree to test; testing results, number of confirmatory tests; number of confirmed HIV positive clients linked to medical care. Enter data into database. Document data. Submit findings to OAPP.	Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	Review and revise, as needed, documentation forms for Partner Counseling and Elicitation Interviews, consent forms, clients logs. Submit to OAPP for approval.	1
5/18/04 and ongoing	By 6/18/04	5/18/04 and ongoing	5/18/04 and ongoing	By 6/18/04	TIMELINE
1A.2	14.1	1.3	1.2)ment *	0
Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	TIMELINE METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

EXHIBIT F-1 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County.

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	3.0			2.0	
	By 12/31/04, 100% of clients completing a Rapid Test will receive disclosure services.			By 12/31/04, a minimum of 127 partners of HIV positive clients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S)
	3.1	2.3	2.2	2.1	
	Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	Administer a brief risk assessment survey. Document client's refusal of Rapid Testing. Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	Schedule HCT activities and maintain calendar of sites, dates, and times.	Review and revise, as needed, Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	PLEMENTATION ACTIVITIES
	By 6/18/04	5/18/04 and ongoing	5/18/04 and ongoing	By 6/18/04	TIMELINE
	<u>:</u>	2.3	2.2	2.1	0
	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	TIMELINE METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

EXHIBIT F-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

Goal No. 1: To provide client-centered Rapid HIV Counseling, Testing and Partner Counseling and Referral Services (PCRS) to patients in Service Planning Areas (SPAs) 1 through 8 of Los Angeles County,

1A.2 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	IA.2 Conduct Partner Notification Sessions with identified partners of HIV positive clients. Document type of partner referral conducted and topics discussed during session. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	
IA.1 Letter(s) of OAPP approval and related material will be kept on file.	By 2/1/05	1A.1 Develop documentation forms for Partner Notification sessions, consent forms, clients logs. Submit to OAPP for approval.	1A.0 By 12/31/05,a minimum of 75% of identified partners of HIV positive clients will receive a partner notification session.
1.3 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	1.3 Complete Client Log. Lob to include, but not be limited to the following; number of partners identified, number of partners who agree to test; testing results, number of confirmatory tests; number of confirmed HIV positive clients linked to medical care. Enter data into database. Document data. Submit findings to OAPP.	
1.2 Completed materials will be kept on file and results documented in monthly reports to OAPP.	1/1/05 and ongoing	1.2 Conduct Partner Counseling and Elicitation Interviews with HIV positive clients. Document type of partner referral to be conducted. Partner notification services can be provided in one of the following formats: Dual-Referral or Provider-Only Referral.	
1.1 Letter(s) of OAPP approval and related material will be kept on file.	By 2/1/05	1.1 Develop documentation forms for Partner Counseling and Elicitation Interviews, consent forms, clients logs. Submit to OAPP for approval.	1.0 By 12/31/05, a minimum of <u>500</u> HIV positive clients will be offered Partner Counseling and Elicitation Services.
METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION	TIMELINE	IMPLEMENTATION ACTIVITIES	MEASURABLE OBJECTIVE(S)
patients in Service Planning Areas (SPAs) I through 8 of Los Angeles County.	lents in Service Pia	Counseling and Kelerral Services (PCKS) to	Coarro. 1. To provinc chenescentered napid the confiscing, resting and rathler

EXHIBIT F-2 SCOPE OF WORK

The Contractor shall achieve the following goals and objectives. Objectives are achieved by following the work plan, composed of implementation and evaluation activities. Activities are to be completed according to the stated timelines and are to be documented as specified.

3.0 By 12/31/05, 100% of clients completing a Rapid Test will receive disclosure services.			2.0 By 12/31/05, a minimum of 255 partners of HIV positive clients will receive a brief risk assessments and be offered a Rapid HIV test.	MEASURABLE OBJECTIVE(S) MEASURABLE OBJECTIVE(S) IMPLEMENTATION ACTIVITIES
3.1 Conduct Disclosure Counseling Session. Document topics discussed. Enter data into PDA. Submit findings to OAPP.	2.3 Administer a brief risk assessment survey. Document client's refusal of Rapid Testing . an Record data on iPAQ Personal Computers (PDAs). Submit findings to OAPP.	2.2 Schedule HCT activities and maintain calendar of sites, dates, and times.	2.1 Develop Rapid HIV Testing and Counseling and protocol and health educational materials. Protocol should contain standard practice guidelines for conducting the following: Risk Assessments; HIV Prevention Counseling; Rapid HIV Tests, Disclosure Counseling Sessions, Follow-up on Linked Referrals, and PCRS services. Submit protocol to OAPP for approval.	IMPLEMENTATION ACTIVITIES
By 2/1/05 3.1	1/1/05 2.3 and ongoing	1/1/05 2.2 and ongoing	By 2/1/05 2.1	TIMELINE
Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Completed materials will be kept on file and results documented in monthly reports to OAPP.	Letter(s) of OAPP approval and related material will be kept on file.	TIMELINE METHOD(S) OF EVALUATING OBJECTIVE(S) AND DOCUMENTATION

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AMBULATORY OUTPATIENT MEDICAL SERVICES AGREEMENT

Amendment No. 9

	THIS AMENDMENT is made a	and entered into this day
of _	, 20	004,
	by and between	COUNTY OF LOS ANGELES (hereafter "County"),
	and	NORTHEAST VALLEY HEALTH CORPORATION (hereafter "Contractor")

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME AMBULATORY OUTPATIENT MEDICAL SERVICES", dated March 3, 1998, and further identified as Agreement No. H-209014, and any Amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend Agreement and provide the changes set forth herein; and

WHEREAS, funds received under the CARE Act will be utilized to supplement, not supplant, State, federal, or local funds made available in the year for which funding is awarded to provide HIV-related services to individuals with HIV disease.

WHEREAS, as a recipient of CARE Act funds, Contractor will participate in the Los Angeles County Eligible
Metropolitan Area (EMA) HIV continuum of CARE.

WHEREAS, as a recipient of CARE Act funds, where there is a Service Provider Network (SPN) in the Service Planning Area (SPA) in which Contractor provides services, Contractor's active participation in the SPN planning and coordination activities is expected and required.

WHEREAS, as a recipient of CARE Act funds, Contractor must implement a "consumer advisory committee" with regular meetings and consumer membership as a mechanism for continuously assessing client need and adequacy of Contractor's services, and to obtain client feedback.

WHEREAS, as a recipient of CARE Act funds, Contractor must actively collaborate and recruit referrals from service organizations and agencies beyond the Ryan White CARE Act service delivery system, including, but not limited to, substance abuse, mental health, primary health care and social services organizations.

WHEREAS, as a recipient of CARE Act funds, Contractor's referrals to and from organizations must be noted and tracked in the Office of AIDS Programs and Policy (OAPP) service utilization data system, and followed up in cases where client

does not make or present for appointment in accordance with Contractor's referral guidelines.

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties agree as follows:

- 1. This Amendment shall be effective the date of Board approval.
- 2. The first paragraph of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
 - "1. TERM: The term of this Agreement shall commence on March 3, 1998 and continue in full force and effect through February 28, 2005, with two (2) twelve (12) month periods, effective March 1, 2005 through February 28, 2006 and March 1, 2006 through February 28, 2007 and one (1) six (6) month period effective March 1, 2007 through August 31, 2007. If such funding is not forthcoming, this agreement shall terminate on February 28, 2005. This Agreement may be terminated, with or without cause, by Contractor upon giving of at least thirty (30) calendar days' advance written notice thereof to County. In any event, County may terminate this

Agreement in accordance with the <u>TERMINATION</u> Paragraphs of the ADDITIONAL PROVISIONS hereunder."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
 - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A, H, I, J, K, L, M, N, O, P Q, R, S, T, U, V, W, X, Y, Z, AA, BB, and CC, attached hereto and incorporated herein by reference."
- 4. Paragraph 3, MAXIMUM OBLIGATION OF COUNTY,
 Subparagraphs H, I, J, and K, shall be added to Agreement as
 follows:
 - "H. During the period date of Board approval through February 28, 2005, the maximum obligation of County for all services provided hereunder shall not exceed Thirteen Thousand Seven Hundred Fifty Dollars (\$13,750). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 39, attached hereto and incorporated herein by reference. Such funds shall be

used entirely for the Special Projects of National Significance, Prevention with Positives Services.

- I. During the period March 1, 2005 through February 28, 2006, the maximum obligation of County for all services provided hereunder shall not exceed Fifteen Thousand Dollars (\$15,000). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 40, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.
- J. During the period March 1, 2006 through February 28, 2007, the maximum obligation of County for all services provided hereunder shall not exceed Fifteen Thousand Dollars (\$15,000). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS). This sum represents the total maximum obligation of County as shown in Schedule 41, attached hereto and incorporated herein by reference.

Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services.

- K. During the period March 1, 2007 through August 31, 2007, the maximum obligation of County for all services provided hereunder shall not exceed Eight Thousand, Seven Hundred Fifty Dollars (\$8,750). Such maximum obligation is comprised entirely of Health Resources and Services Administration (HRSA), Special Projects of National Significance (SPNS) funds. This sum represents the total maximum obligation of County as shown in Schedule 42, attached hereto and incorporated herein by reference. Such funds shall be used entirely for the Special Projects of National Significance, Prevention with Positives Services."
- 5. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
 - "6. COMPENSATION: County agrees to compensate

 Contractor for performing services hereunder for

 reimbursable net cost as set forth in Schedules 1, 2, 3,

 4, 8, 10, 13, 14, 15, 17, 21, 22, 23, 26, 27, 30, 31, 34,

 35, 37, 38, 39, 40, 41, and 42, and on a fee-for-service

 basis as set forth in Schedules 5, 6, 7, 9, 11, 12,16,

- 18, 19, 20, 24, 25, 28, 29, 32, 33, and 36, and the FEE-FOR-SERVICE REIMBURSEMENT Paragraph of this Agreement."
- 6. Exhibit CC, SCOPE OF WORK FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE, PREVENTION WITH POSITIVES SERVICES, is attached to this Amendment and incorporated in Agreement by reference.
- 7. Schedules 39, 40, 41, and 42, BUDGETS FOR SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE, PREVENTION WITH POSITIVES SERVICES, are attached to this Amendment and incorporated in Agreement by reference.
- 8. Except for the changes set forth hereinabove,
 Agreement shall not be changed in any respect by this
 Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

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Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COU	JNTY OF LOS ANGELES
Ву	m) To G
	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
NOF	RTHEAST VALLEY HEALTH CORPORATION
	Contractor
Ву	
	Signature
	Printed Name
Tit	cle
	(AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

APPROVED AS TO CONTRACT ADMINISTRATION:

Department of Health Services

By ______ Irene E. Riley, Director Contract Administration

EXHIBIT CC

NORTHEAST VALLEY HEALTH CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS)
PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED
PERSONS SEEN IN PRIMARY CARE SETTINGS
(PREVENTION WITH POSITIVES)

1. DEFINITIONS:

- A. Immune deficiency caused by the Human

 Immunodeficiency Virus (HIV) is a spectrum of disease

 which ranges from asymptomatic HIV disease to Acquired

 Immune Deficiency Syndrome (AIDS) as defined by the

 Federal Centers for Disease Control and Prevention (CDC).
- B. The U.S. Health Resources and Services

 Administration (HRSA) funds Special Projects of National

 Significance (SPNS) to explore HIV/AIDS care and

 treatment best practices, innovative service methods and

 system improvements. In 2003, HRSA launched a SPNS

 initiative seeking new projects to demonstrate the

 effectiveness of prevention education for people with

 HIV/AIDS in primary health care settings. Los Angeles

 County's Office of AIDS Programs and Policy (OAPP)

 received one of 15 SPNS Prevention with Positives grant

 awards nationwide.

C. "Prevention with Positives" encompasses the spectrum of prevention education activities targeting people who are HIV-positive. Providing prevention education and eliciting the involvement of HIV-positive people in the effort to stem the HIV infection rate is a key priority of the U.S. Centers for Disease Control (CDC). Prevention with Positives activities can take place in a variety of settings; the SPNS initiative focuses on the primary health care setting.

HRSA defines Prevention with Positives activities directed by the primary providers (e.g., physicians, nurses, etc.) as "provider-based", and those activities directed by others at service sites as "specialist-based". The OAPP demonstration project uses the "provider-based" model.

D. "Intervention" describes the proposed
"prevention for positive" education that to be used in
the new demonstration model. "Evaluation" defines those
activities conducted to measure the effectiveness of the
intervention. Those clinics incorporating the
intervention into their regular, ongoing medical visits
and participating in the evaluation are "intervention

- sites". The clinic not using the intervention, but participating in the evaluation is the "control site."
- 2. PERSONS TO BE SERVED: All HIV-positive clients receiving medical services at contracted intervention sites will be given Prevention with Positives education during their medical appointments, in accordance with directions from the project training and as described hereunder in following sections.

All contracted clinics will be required to help project evaluators identify a minimum of 150 medical clients for participation in evaluation activities, as described hereunder in following sections.

3. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period date of Board approval through August 31, 2007, that portion of County's maximum obligation which is allocated under this Exhibit for participation in the SPNS-funded Prevention with Positives Demonstration Project shall not exceed Fifty-Two Thousand, Five Hundred Dollars (\$52,500).

4. COMPENSATION:

A. County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedules 39, 40, 41, and 42.

- B. County agrees to compensate Contractor for allowable reimbursable costs associated with participation in the SPNS-funded Prevention with Positives Demonstration Project, in accordance with the budgets set forth in Schedules 39, 40, 41, and 42, attached hereto and incorporated herein by reference, as the budgetary items currently exist or as they are modified in the future by the Office of AIDS Programs and Policy (OAPP).
- C. Payment for services provided hereunder shall be subject to the provisions set forth in the COST REIMBURSEMENT Paragraph of this Agreement.
- 5. <u>CLIENT/PATIENT ELIGIBILITY</u>: Contractor shall ensure that all client participants are HIV-infected and that their serostatus is documented in each client's medical record.
- 6. <u>SERVICE DELIVERY SITE</u>: During the period of this Agreement, Contractor's facility where participation in the demonstration project will be conducted is at: 1172 North Maclay Avenue, San Fernando, California 91340.

Contractor shall request approval from OAPP in writing a minimum of thirty (30) days before moving location(s) of demonstration project participation.

- 7. SERVICES TO BE PROVIDED/SCOPE OF WORK: During each term of this Agreement, as specified in Exhibit CC, for purposes of participation in the Prevention with Positives Demonstration Project, Contractor will serve as one of two intervention sites to be studied. All provider sites will, from time to time, be required to participate in project-related meetings and/or other events, as appropriate and necessary. Participating as the control site entails the following services and activities:
 - A. <u>Evaluation</u>: Contractor shall participate in all project evaluation activities, to include, but not limited to:
 - Referring appropriate clients to interviewers for recruitment into the project evaluation;
 - 2) Providing adequate, private, secure space
 for interviewing and data entry, and storage (if
 required by Contractor);
 - 3) Facilitating Institutional Review Board (IRB) process if required specifically for the Contractor:

- 4) Assisting with the screening and securing client consents when and wherever appropriate and possible;
- 5) Preparing and adhering to charting, documentation and other operational procedures as outlined in the project design;
- 6) Providing appropriate documentation when and where needed as required to support evaluation, data entry and subsequent analysis;
- 7) Coordinating the recruitment of Contractor personnel to participate in qualitative provider interviews;
- 8) Helping to recruit clients to participate in project focus group activities, as needed and appropriate.

The project evaluation is a three-year effort and will begin in the latter half of the project's first year.

8. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following report(s):

- A. <u>Monthly Report</u>: Contractor shall submit to OAPP a monthly report together with an invoice no later than thirty (30) days after the end of each calendar month.

 Monthly reports shall clearly reflect all required information as specified on the monthly report form provided by OAPP.
- B. <u>Semi-Annual</u>: Contractor shall submit to OAPP a semi-annual report within the time period as directed for each six month period. Semi-annual reports shall include all the required information and be completed in the correct format.
- C. Annual Report: Contractor shall submit to OAPP an annual report within the time period as directed for each year. Annual reports shall include all the required information and be completed in the correct format.
- 9. QUALITY MANAGEMENT: Contractor shall implement a Quality Management (QM) program that assesses the extent to which the care and services provided are consistent with Federal (e.g., Public Health Services and CDC Guidelines), state, and local standards of HIV/AIDS care and services. The QM program shall at a mimimum: 1) Identify leadership and accountability of the medical director or executive director, 2) Use measurable outcomes and data collected to determine

progress toward established benchmarks, 3) Focus on linkages to care and support services and client perception pertaining to their health and the effectiveness of the service received, 4) Be a continuous quality improvement (CQI) process reported to senior leadership annually.

A. Quality Management Plan: Contractor shall base its program on a written QM plan. Contractor shall develop one agency-wide QM plan that encompasses all HIV/AIDS care and prevention services if possible. The QM plan is to be submitted to OAPP at the beginning of a contract term. The plan shall be reviewed and updated annually by agency's QM committee and signed by the medical director or executive director. QM plan and program, will be reviewed by OAPP staff during the QM program review.

The written Quality Management plan shall at a minium include the following components:

- 1) Objectives: QM plan should delineate specific goals and objectives that are in line with the program's mission, vision and values.
- 2) <u>OM Committee</u>: Describes the purpose of the committee, composition, meeting frequency, at a minimum quarterly, and required documentation (e.g.,

minutes, agenda, sign-in sheet, etc.). A separate Committee need not be created if the contracted program has established an advisory committee or the like, so long as its composition and activities conform to the QM program objectives.

3) <u>Selection of a QM Approach</u>: Describes the QM approach, such as Plan-Do-Study-Act (PDSA), Chronic Care Model or Joint Commission on Accreditation of Healthcare Organization (JCAHO) 10-Step model, etc.

4) OM Program Content:

- a. Measurement of Outcome Indicators at a minimum, collection and analysis of data measured from the specific OAPP selected indicators. In addition, contractor can measure other aspects of care and services as needed.
- b. Development of Data Collection Method to include sampling strategy (e.g., frequency,
 percentage of sample size), collection method
 (e.g., chart abstraction, interviews, surveys,
 etc.), and creation of a data collection tool.
- c. Collection and Analysis of Data results to be reviewed and discussed by the QM

committee. The findings of the data analysis are to be communicated with all program staff involved.

- d. Identify and Sustain Improvement QM committee shall be responsible for identifying improvement strategies, tracking progress, and sustaining the improvement achieved.
- 5) Random Chart Audits (Medical Outpatient, Medical Nutrition, Case Management, Mental Health, Psychiatry, and Dental Providers of Care Services):

 Sampling criteria shall be based on important aspects of care and shall be, at a minimum, 10% or 30 charts, whichever is less. Results of sampling to be reported and discussed in the QM committee quarterly.
- 6) Client Feedback Process: The QM plan shall describe the mechanism for obtaining ongoing feedback regarding service effectiveness, efficacy, accessibility, and satisfaction. Client input obtained shall be discussed at the QM Committee on a regular basis for the enhancement of the service delivery. Aggregated data is to be reported to the

QM committee annually for continuous program improvement.

- 7) Client Grievance Process: Contractor shall establish policy and procedure for addressing and resolving client's grievances at the level closest to the source within agency. The grievance data is to be tracked, trended, and reported to the QM committee for improvements of care and services. The information is to be made available to QM staff during program reviews.
- B. Quality Management Program: To determine the compliant level, OAPP shall review contractor's QM program annually. A numerical score will be issued to the contractor's QM program based on 100% as the maximum score. Contractor's QM program shall be assessed for implementation of the following components:

OM Program Objectives

QM Committee

Selection of a QM Approach

QM Program Content

Random Chart Audit (if applicable

Client Feedback Process

Client Grievance Process

NORTHEAST VALLEY HEALTH CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

Date	Budget Period of Board Approval through February 28, 2005
Salaries	\$ 10,315
Employee Benefits	\$ 2,785
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 13,100
Indirect Cost	\$ 650
TOTAL PROGRAM BUDGET	\$ 13,750

NORTHEAST VALLEY HEALTH CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	Budget Period March 1, 2005 through February 28, 2006
Salaries	\$ 11,253
Employee Benefits	\$ 3,085
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 14,338
Indirect Cost	\$ 662
TOTAL PROGRAM BUDGET	\$ 15,000

NORTHEAST VALLEY HEALTH CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	<u>Budget Period</u>
	March 1, 2006
	through
	February 28, 2007
Salaries	\$ 11,253
Employee Benefits	\$ 3,151
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$ 14,404
Indirect Cost	\$ 596
TOTAL PROGRAM BUDGET	\$ 15,000

NORTHEAST VALLEY HEALTH CORPORATION

SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE (SPNS) PREVENTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)-INFECTED PERSONS SEEN IN PRIMARY CARE SETTINGS (PREVENTION WITH POSITIVES)

	March	et Period n 1, 2007 through 31, 2007
Salaries	\$	6,564
Employee Benefits	\$	1,838
SUBTOTAL SALARIES AND EMPLOYEE BENEFITS	\$	8,402
Indirect Cost	\$	348
TOTAL PROGRAM BUDGET	\$	8,750